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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Ninth Circuit Rule 26.1, Plaintiff-Appellee Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF") hereby states that it is a non-profit corporation organized under the laws of the State of Montana. R-CALF has no parent corporation, and no publicly traded company owns 10 percent or more of the stock of R-CALF.

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STATEMENT OF ISSUES

Defendants-Appellants U.S. Department of Agriculture, *et al.* ("USDA") mischaracterize the issues properly before this Court in USDA's appeal of the District Court's March 2, 2005 issuance of a preliminary injunction (the "Preliminary Injunction"). Plaintiff-Appellee Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF") proposes the following issues:

1. Whether the District Court committed an abuse of discretion when it found R-CALF has a probability of successfully showing that USDA's rule allowing imports of cattle and beef from Canada, 70 Fed. Reg. 460 (January 4, 2005) (the "Final Rule"), was inconsistent with and not supported by the facts in the Administrative Record?

2. Whether the District Court committed an abuse of discretion in finding that the implementation of the Final Rule on March 7, 2005 would have resulted in irreparable injury to R-CALF's members or, in the alternative, that the balance of harms tips strongly in R-CALF's favor?

STATEMENT OF THE CASE

While R-CALF agrees with portions of the Statement of the Case in USDA's opening brief, it leaves out a few key aspects of the proceedings below. For many years, USDA has had a strict policy of prohibiting imports of cattle and beef from any country where bovine spongiform encephalopathy ("BSE") is known to exist. *See* 70 Fed. Reg. at 462.[1] That policy initially was applied to Canada on May 29, 2003, 68 Fed. Reg. 31,939, after the discovery of BSE in a native-born Canadian cow.

Under intense pressure from the Canadian government and some U.S.-based meat packers (who also operate packing plants in Canada), on August 8, 2003, the Secretary of Agriculture announced that USDA would grant blanket permits for the importation of certain meat products from Canada that were judged to be of low risk. *See* 70 Fed. Reg. at 536; District Court's March 2, 2005 opinion supporting its preliminary injunction order ("Op.") at 3 (ER110). R-CALF later learned that USDA, without any notice to the public, was allowing other, higher-risk bovine products from Canada. On April 26, 2004, at R-CALF's request, the District Court issued a

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[1] Federal Register notices to which the Court may need to refer are included in the Addendum to this brief, except for the challenged regulation, which USDA included in its Excerpts of Record ("ER") at 183.

Temporary Restraining Order, prohibiting importation from Canada of all edible bovine meat products beyond those authorized by USDA's action of August 8, 2003. *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. United States Dept. of Agriculture, et. al.*, No. CV-04-51-BLG-RFC, Supplemental Excerpts of Record ("SER") at 125.

USDA's Statement of the Case also omits the fact that, prior to the March 2, 2005 preliminary injunction hearing, seven states, Connecticut, New Mexico, North Dakota, Montana, Nevada, South Dakota, and West Virginia filed an *amicus curiae* brief supporting the grant of a preliminary injunction. (Docket # 29.)

STATEMENT OF FACTS

In its description of the development of the BSE problem in Canada, USDA omits the fact that, once BSE was discovered in a native Canadian cow in May 2003, the United States' largest beef export trading partner, Japan, threatened to ban imports of US beef unless that beef was positively identified as not having come from Canadian-origin cattle. *See* 70 Fed. Reg. at 524. Then, after the December 2003 discovery of BSE in a Canadian-raised cow that had been imported to Washington State, Japan, Korea, Taiwan, and most of the other countries to which the U.S. exports beef

banned imports of US beef because of fears that BSE had entered the United States from Canada. This had a devastating effect on U.S. exports of beef, reducing that market by billions of dollars per year. 70 Fed. Reg. at 521. Those markets remained largely closed to U.S. exports of beef even now. 70 Fed. Reg. at 524-25.

SUMMARY OF ARGUMENT

In an attempt to avoid the limited scope of appellate review of a district court's decision to grant a preliminary injunction, USDA claims that the District Court applied the wrong legal standards, and therefore its decision should be reviewed by this Court *de novo*. In fact, however, the record shows that the District Court applied the correct legal standards and conducted a careful inquiry into the arguments for and against issuance of a preliminary injunction. USDA merely disagrees with the District Court's factual determinations of whether USDA's actions and conclusions were consistent with USDA's explanations and with other information in the administrative record.

Certainly USDA's disagreements with the District Court's conclusions are a far cry from a showing that the District Court abused its discretion. USDA's brief largely restates arguments that the District Court considered,

questioned the parties about at the preliminary injunction hearing, and ultimately rejected. R-CALF demonstrated it had a substantial likelihood of showing that USDA's actions were inconsistent with the Administrative Procedure Act, the National Environmental Policy Act, and the Regulatory Flexibility Act. Like its rulemaking, USDA's brief relies on overstatements or misstatements of the underlying record, as well as arguments and facts that were never even presented below.

USDA also disagrees with the conclusions the District Court reached when it weighed the short-term financial disadvantage to meat packers and others seeking access to cheap Canadian cattle and beef prior to the District Court's review of the Final Rule, versus the threatened and anticipated risks to the health and financial well-being of the United States' cattle-producing industry and to U.S. consumers once the Final Rule relaxed the prohibition on imports of cattle and beef from a country known to have BSE. The fact that USDA disagrees with the District Court's conclusion that preservation of the *status quo* best balances the harms, however, does not constitute a demonstration that there was an abuse of discretion by the District Court.

ARGUMENT

I. USDA Misapprehends this Court's Role in Reviewing a Preliminary Injunction.

A. The District Court's action should be reviewed for abuse of discretion, rather than *de novo*.

This Court's review of the issuance of a preliminary injunction "is limited and deferential." *Harris v. Board of Supervisors, Los Angeles County*, 366 F.3d 754, 760 (9th Cir. 2004) (quotations and citations omitted). USDA acknowledges this deferential standard of review, USDA Br. at 19, but nevertheless states its issues in terms simply of whether the District Court "erred," and proceeds to argue in depth why it believes the District Court should have reached different conclusions about whether USDA had adequately explained and supported its action.

USDA is implicitly asserting that all of these determinations were errors of law. *See* USDA Br. at 19. There is no basis, however, for USDA to claim that the District Court applied the wrong standard of review either

for granting a preliminary injunction or for judging whether R-CALF had a possibility of succeeding on the merits.[2]

USDA apparently agrees with the District Court's formulation of the standards for issuing a preliminary injunction, using almost identical language. *Cf.* USDA Br. at 19 *with* Opinion at 6 (ER113). The District Court correctly stated the "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" standard of review that would apply in judging R-CALF's likelihood of success on the merits, acknowledging that this standard is a narrow one and that the reviewing court may not merely substitute its judgment for that of the agency. Opinion at 7 (ER114). The District Court also noted numerous other precedents of this Court and the Supreme Court that indicate that, despite the narrow "arbitrary and capricious" standard of review, the reviewing court still must carefully review the basis for the agency's action and determine whether that action was consistent with the facts before the agency, arrived at by applying appropriate factors, adequately explained, and so forth. *Id.* at 7-8 (ER114-15).

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[2] As the District Court correctly noted, case law in the Ninth Circuit provides for the issuance of a preliminary injunction, where the potential for harm if the *status quo* is not preserved is great, even if there is less than a likelihood of success on the merits. Op. at 6 (ER113).

Thus, this is not a case where there was an "erroneous legal premise," where *de novo* review is appropriate. *See Harris*, 366 F.3d at 760. Once this Court determines that "the district court employed the appropriate legal standards which govern the issuance of a preliminary injunction, and ...correctly apprehended the law with respect to the underlying issues in the litigation," its "inquiry is at an end." *Id.*, quoting *Southwest Voter Registration Educ. Project v. Shelley*, 344 F.3d 914, 918 (9th Cir. 2003) (en banc).

The fact that the District Court reached conclusions about USDA's rulemaking that USDA believes were not sufficiently deferential to it does not change USDA's critiques of the District Court's judgments into a question of law that requires or permits this Court's *de novo* review of those judgments.[3] The District Court's assessment of the probability of R-CALF's success on the merits must be reviewed for abuse of discretion, without getting into "the underlying merits of the case." *Harris*, 366 F.3d at 760 (quotations and citations omitted).

USDA seems to want this Court to try the case, *de novo*, and before the case has even been tried below. As the Court recently observed:

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[3] The District Court's conclusions were factual ones. *See, e.g.*, Opinion at 11, 12-13, (ER118, 119-20).

> We typically will not reach the merits of the case when reviewing a preliminary injunction.... [W]e will not second-guess whether the court correctly applied the law to the facts of the case, which may be largely undeveloped at the early stages of litigation. As long as the District Court got the law right, it will not be reversed simply because the appellate court would have arrived at a different result if it had applied the law to the facts of the case.

Earth Island Inst. v. U.S. Forest Service, 351 F.3d 1291, 1298 (9th Cir. 2003) (quotations omitted). In fact, as the case on which USDA primarily relies, *Clear Channel Outdoor, Inc. v. City of Los Angeles*, 340 F.3d 810 (9th Cir. 2003), explains, a plaintiff may not need to show that it is more likely than not to succeed on the merits: "the greater the relative hardship...the less probability of success must be shown." *Id.*; *see also Earth Island*, 351 F.3d at 1298.

B. The District Court applied the appropriate standards for granting a preliminary injunction.

As noted above, the District Court correctly stated (and applied) the criteria for issuance of a preliminary injunction under this Court's jurisprudence. Op. at 6, 25-26 (ER113, 132-33). The District Court also correctly stated (and applied) the standard of review applicable to its determination of the probability of R-CALF's success on the merits of its claims under the Administrative Procedure Act, National Environmental Policy Act, and Regulatory Flexibility Act, which is one of the criteria for

granting a preliminary injunction. Op. at 7-8, 13-14, 17, 18-19, 21, 22 (ER114-15, 120-21, 124, 125-26, 128, 129).

USDA argues that the District Court was required to apply a highly deferential standard when reviewing USDA's judgments inherent in the Final Rule. But the District Court correctly pointed out that this still means that the reviewing court must "carefully review" the record and whether the agency decision reflects "a recent evaluation of the relevant factors." The deferential standard of review does not mean that a court should "rubber stamp" an agency decision, especially with respect to a decision that might result in increased risk to human health. Op. at 7-8 (ER114-15).

An agency acts arbitrarily and capriciously when it does not articulate a "rational basis" for its conclusions. *NAHB v. Norton*, 340 F.3d 835, 841 (9th Cir. 2003). In *Sierra Club v. EPA*, 346 F.3d 955 (9th Cir. 2003) this Court explained: "While our deference to the agency is significant, we may not defer to an agency decision that "is without substantial basis in fact." *Id.* at 961 (*quotation and citation omitted). See also, e.g., Ariz. Cattle Growers' Ass'n v. United States Fish & Wildlife Service*, 273 F.3d 1229, 1236 (9th Cir. 2001); *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998) (court need not forgive a clear error of judgment); *Sierra Club v. EPA*, 346 F.3d 955, 961 (9th Cir. 2005) (no deference to

agency judgment where agency offered an explanation that ran counter to the evidence).

USDA argues that it is entitled to rely on the views of its own experts, and the reviewing court cannot reject USDA's conclusions because other experts have differing views. USDA Br. at 22. But here, as the discussion below will demonstrate, the conflicting views largely came from USDA's own experts, and from the expert reports upon which USDA claimed to rely.

In addition, the District Court had before it an audit report recently published by USDA's Office of Inspector General ("OIG"), describing the OIG's audit of USDA's oversight of the importation of beef products from Canada after the May 2003 detection of BSE in a native Canadian cow. *See id.* ("Audit Report") at i (SER206).[4] The Audit Report indicates numerous instances where USDA expanded imports from Canada based on a desire to respond to industry requests to expand trade, rather than on scientific

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[4] The District Court could take judicial notice of this official document. *See, e.g., Blair v. City of Pamona*, 223 F.3d 1074 (2000) (taking judicial notice of Christopher Commission report on police misconduct in Los Angeles); *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994) (report of an administrative body); *Military Toxics Project v. EPA*, 146 F.3d 948, 954 (D.C. Cir. 1988) (taking notice of a "policy document from the EPA and two reports from the General Accounting Office" appended to brief that were "not part of the administrative record.").

principles that showed the products or Canadian establishments presented minimal risk.[5]

Although the District Court opinion does not refer directly to the Audit Report, it clearly supports the District Court's conclusion that:

> The facts strongly suggest that the USDA, ignoring its statutory mandate to protect the health and welfare of the people of the United States, established its goal of re-opening the border to the importation of live beef from Canada and thereafter attempted to work backwards to support and justify this goal.

Op. at 11-12 (ER118-19); *see also* Op. at 26-27 (ER133-34) ("USDA has evidenced a preconceived intention, based upon inappropriate

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[5] For instance, the Audit Report explains that in October 2003 USDA listed certain edible bovine products on a chart of eligible "low-risk" Canadian products, without explaining why these products were considered to be low-risk, especially when the APHIS Transmissible Spongiform Encephalopathy (TSE) Working Group had concluded that some of the products, e.g. bovine tongues and bone-in beef, were "moderate risk." *See* Audit Report at 10-12 (SER223-225). The Audit Report shows that USDA officials desired to satisfy "industry concerns that permit policies were too restrictive for trade" instead of using careful, reasoned scientific judgments to conclude that certain products presented minimal risks. *See id.* at 7-8, 10 (SER 220-221, 223); *see also id.* at 12 (SER225) (APHIS clandestinely allowed imports of bone-in beef beginning November 2003, but "did not ... provide any documentation to explain why these products were considered low-risk"). In fact, the APHIS TSE Working Group concluded that even boneless cuts of meat were only "low risk" if from animals under 24 months of age, *and* if other mitigation measures had been implemented. *See* APHIS TSE Working Group Memorandum (June 16, 2003) at AR009392C, AR009392F, AR009392I (SER58, 61, and 64).

considerations, to rush to reopen the border regardless of uncertainties in the agency's knowledge of the possible impacts....").

The District Court's factual conclusions about USDA's preconceived intention to resume trade with Canada have not been shown to constitute clear error, and they justify not applying the presumption of deference to USDA decisions concerning imports from Canada. *Gifford Pinchot Task Force v. U.S. Fish and Wildlife Service*, 378 F.3d 1059 (9th Cir. 2004) (improprieties in process overcame presumption that administrative record was complete); *Ariz. Cattle Growers' Ass'n*, 273 F.3d at 1236 (no deference to agency action inconsistent with statutory mandate and congressional policy).

C. The District Court did in fact conduct a careful review, consistent with the purposes of a preliminary injunction hearing.

The purpose of a preliminary injunction is to preserve the *status quo* until there has been sufficient opportunity for a full determination on the merits. The district court's review of the issues presented necessarily must be more limited than in the merits proceeding. That fact does not, however, mean that all agency actions supported by an administrative record are immune from preliminary injunctions. R-CALF's assertion that it was likely to succeed on the merits of its claims was supported by extensive briefing,

with reference to declarations of a number of experts, numerous articles from peer-reviewed scientific journals, and, to a great extent, statements in USDA's own documents. Judge Cebull admonished counsel, both before and during the hearing, that he had read every word of the briefs filed in the case, and he had made extensive notes from his review of portions of the Administrative Record. Tr. at 4, 48 (SER281).

The transcript of the hearing confirms that, far from accepting R-CALF's assertions uncritically, Judge Cebull probed the positions of both R-CALF and USDA carefully during the course of a hearing that lasted half a day. *See, e.g.,* excerpts of Transcript provided at SER248-311. The Court inquired of USDA why the European countries and Japan remove potentially higher-risk tissues from cattle at an earlier age than do Canada and the U.S., for example. Tr. at 86-87 (SER308-309). The Court also understood and asked questions about USDA's and R-CALF's arguments about the incidence of BSE and was familiar with the history of BSE in Canada. *See* Tr. at 52-58 (SER285-291). He also asked pointed questions concerning the significance of the time the "feed ban" has been in place. Tr. at 59-60. These circumstances provide no basis at all for this Court's delving into the District Court's determinations.

D. This Court should not consider arguments and evidence not presented to the District Court.

USDA's brief contains numerous arguments and refers to many statements in the nearly 13,000-page Administrative Record that were not presented to the District Court in connection with its consideration of R-CALF's application for a preliminary injunction. This Court should not consider those arguments or that "evidence."

For example, USDA argues that the applicable statute gives the Secretary of Agriculture unfettered discretion to decide when to prohibit or restrict imports of livestock, and therefore his decision may not even be judicially reviewable. USDA Br. At 20-21. USDA further argues that a Conference Report on 2002 legislation supports that position. None of those arguments or references were presented to the District Court, and they therefore should not have been argued here as grounds for overturning the District Court's decision. *See, e.g., Brown v. City of Tucson*, 336 F.3d 1181, 1187 n.11 (9th Cir. 2003); *Swift v. California*, 384 F.3d 1184, 1193 (9th Cir. 2004) (refusing to consider legal arguments "which should be addressed by the district court in the first instance"); *United States v. Alisal Water Corp.*, 370 F.3d 915, 923 (9th Cir. 2004).

Similarly, USDA's brief contains many references to material that was not presented at the District Court level.[6] Indeed, some of its references did not even *exist* at the time of the preliminary injunction hearing. *See, e.g.*, USDA Br. at 29, 59. In effect, it asks this Court to re-try this case, based on arguments and references not presented to the court below. For obvious reasons, this Court repeatedly has declined to engage in such an exercise. *See, e.g., Palidin Assocs., Inc. v. Montana Power Corp.*, 328 F.3d 1145, 1153 n.4 (9th Cir. 2003); *S.O.S., Inc. v. Payday, Inc.*, 886 F.2d 1081, 1087 (9th Cir. 1989).

II. The District Court properly found a likelihood of success on R-CALF's claims that USDA violated the Administrative Procedure Act.

A. USDA's abandonment of a key protection against BSE infection in the United States was arbitrary and capricious.

USDA's argument focuses on its assertion that provisions of the Final Rule are sufficient to avoid "a credible threat of dissemination of BSE." *See* USDA Br. at 19-20. But the statutory provision that USDA claims to be

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[6] It would be patently unreasonable, especially at the preliminary injunction stage, to conclude that the District Court abused its discretion by failing to rely on something buried in an administrative record of close to 13,000 pages, filed in 27 binders (*see* Docket Entry #43), or in 85 pages of Federal Register preamble. Indeed, USDA had not even compiled the Administrative Record until weeks after R-CALF USA was required to file its Memorandum in Support of Application for Preliminary Injunction. *Cf. id. with* Docket Entry # 18.

implementing with the Final Rule is one intended to prevent "the introduction into or dissemination within the United States of any pest or disease of livestock." 7 U.S.C. § 8303(a)(1). The fact that USDA's brief focuses on "dissemination," rather than "introduction," of BSE is significant: R-CALF demonstrated that USDA had insufficient information to know the extent to which resuming imports of Canadian cattle will result in the introduction of BSE into the United States, and the Harvard Risk Assessment, upon which USDA primarily relied in issuing the Final Rule, clearly stated that it could not estimate the risk of introduction of BSE into United States. *See* AR008426-27 (SER317-318) ("In the absence of strong evidence about the prevalence of BSE in the Canadian herd, information that would allow us to calculate a probability of introduction, we instead posit a hypothetical introduction of five BSE positive bulls into the U.S.")[7]

USDA policy since 1989 has been to ban imports of cattle from countries where BSE is known to exist (70 Fed. Reg. at 462). Since 1991, USDA also has banned imports of ruminant meat and most bovine products

[7] The Harvard Study in fact was not specific to the Canadian situation, but rather modeled "the consequences of a hypothetical introduction of BSE into the U.S. from Canada" at different times ranging from 1990 to 1998 AR008425 (SER316), concluding that, for these hypothetical situations, in the most likely scenario BSE would almost certainly be eradicated...within 20 years! AR008424 (SER315); 70 Fed. Reg. at 506.

from such countries. 56 Fed. Reg. 63,865 (Dec. 6, 1991). These actions were considered "necessary to reduce the risk that BSE could be *introduced* into the United States." *See id.* at 63,866 (emphasis added); *see also* 56 Fed. Reg. 19,794, 19,795 (April 30, 1991) (most imports of ruminant meat must be banned "to prevent the introduction of BSE into the United States"); 62 Fed. Reg. 65,747, 65,748 (Dec. 16, 1997) (banning imports of live cattle from the Netherlands) ("Preventing the introduction of BSE into the United States is critical"); 66 Fed. Reg. 52,483 (Oct. 16, 2001). USDA concluded that such drastic measures were justified by the nature of BSE:

> BSE is not known to occur in the United States, and its introduction would be a major economic disaster for our animal industries. We believe that due to the drastic consequences of BSE introduction, strict import requirements are justified to control even very low-probability risks of introducing BSE. In addition, due to the long incubation period of BSE and the lack of long-term comprehensive studies of its spread in countries with only a few reported cases, we cannot accurately estimate the extent of BSE in countries with any reported cases.

56 Fed. Reg. at 63,867. *See also id.* at 63,868; 62 Fed. Reg. at 65,748. These very same conditions still exist today, and yet USDA has abandoned the policy of avoiding introduction of BSE into the United States in issuing the Final Rule and allowing imports from a country known to have BSE.

USDA and others have consistently identified the ban on importation of cattle and beef from countries known to have BSE as a key element in protecting domestic cattle from BSE and domestic consumers from vCJD. As recently as a 2003 report to Congress, a federal inter-agency working group convened by the Secretary of Agriculture explained the central role that this ban on imports plays in U.S. efforts to avoid BSE:

> The U.S. approach to managing the risk of BSE is focused on three primary goals:
>
> - *Prevent the agent of BSE from entering* the United States and infecting U.S. cattle;
> - Prevent the amplification of the agent of BSE throughout the U.S. cattle herd, *were it to penetrate the primary firewall at the borders* and infecting U.S. cattle; and
> - Prevent the exposure of Americans to the agent of BSE via food and other products that are fully or partially of bovine derivation.

Animal Disease Risk Assessment, Prevention, and Control Act of 2001 (PL 107-9) Final Report, AR009261 (SER20) (emphasis added). That report to Congress also reiterated the conclusions of the Harvard Risk Assessment, listing the APHIS "ban on the import of live ruminants and ruminant meat and bone meal" from all countries known to have BSE at that time as one of three "key actions [that] have been particularly effective in achieving these goals...." *Id.*; *see also* AR009307 (SER30) ("The U.S. Government's

actions to restrict imports from Europe have played an important role in excluding BSE from this country."). This emphasis on keeping potentially BSE-infected cattle out of the United States reflects the fact that: "the most likely routes of introduction of BSE into the U.S. national herd would be through the importation (either legal or illegal) of: meat and bone meal contaminated with the agent of BSE, or live cattle that are already incubating the disease and then are slaughtered, rendered, and incorporated into domestic meat and bone meal that is mistakenly fed to cattle." *Id.* at AR009303 (SER26).[8]

USDA had a special obligation here to explain why it chose to abandon its prior decision to ban imports of cattle and bovine products from Canada once BSE was discovered in Canada, which reflected USDA policy since 1989 of excluding cattle from countries where BSE is known to exist (70 Fed. Reg. at 462), especially in light of the discovery of several more cases of BSE in Canadian cattle in the interim. *See Nat'l Conservative Political Action Comm. v. FEC*, 626 F.2d 953, 959 (D.C. Cir. 1980); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970), *cert. denied* 403 U.S. 923 (1971). USDA has not explained how the Final Rule is

[8] USDA also repeatedly praised Canada's policy of banning imports of cattle from all countries where BSE is known to exist. *See, e.g.*, 70 Fed. Reg. at 464, 467, 486.

consistent with 7 U.S.C. § 8303(a)(1), given that it abandons prior policies creating the "primary firewall" that prevents the "introduction" of BSE into the U.S., now focusing only on measures to minimize the risk of "dissemination" of the disease once it has entered the country.

B. USDA failed adequately to characterize the risk of resuming Canadian imports.

USDA admitted in the preamble to the Final Rule that it "has set no specific thresholds for an acceptable number of cases in humans or animals." 70 Fed. Reg. at 473. Consistent with applicable case law on review of agency action, the District Court properly concluded that: "Presented with the USDA's conclusions that the risks to U.S. cattle and consumers are "low" without any definition as to what that means and why the risks presented by the Final Rule are acceptable, this Court has no way of assessing the merits of USDA's actions....Therefore, the evidence demonstrates, in all probability, that the USDA's failure to conduct a proper risk assessment, and its failure to articulate any standards by which it has judged the risks of those potentially fatal outcomes to be acceptable, renders its action arbitrary and capricious and unsupported by the record." Op. at 9-10 (ER116-17).

The District Court relied in part on *Ober v. Whitman*, 243 F.3d 1190, 1195 (9th Cir. 2001). In that case, this Court considered the Environmental Protection Agency's judgment that certain levels of particulate emissions are "de minimis." 243 F.3d at 1195. This Court explained that: "Unless [EPA] describes the standard under which [it] has arrived at this conclusion, supported by a plausible explanation, we have no basis for exercising our responsibility to determine whether [EPA's] decision is arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law." *Id.* (citations omitted). That is precisely the factual situation which the District Court found: USDA claimed that the risks presented by the Final Rule are acceptable, but provided no explanation of the standard USDA used to judge the risks acceptable. In fact, USDA admitted that it had not even attempted to determine what an acceptable level of risk to the health of the U.S. cattle and U.S. consumers would be. 70 Fed. Reg. at 473.

During the hearing on the Preliminary Injunction, counsel for USDA acknowledged that the cattle population in Alberta Province "is a high-risk population," compared to other parts of Canada where she alleged "there is no BSE." Tr. at 57 (SER290). When Judge Cebull asked about the significance of the fact that two animals in Canada were discovered with BSE just before and just after the Final Rule was announced, USDA's

counsel responded frankly: "These are a cluster. They have been investigated rigorously."[9]

In fact, as a result of those additional discoveries, USDA suspended a portion of the Final Rule. *See* SER247 and 70 Fed. Reg. 12,112 (March 11, 2005), despite the fact that only weeks earlier USDA has announced confidence in its conclusion that Canadian cattle presented a "low" risk.[10]

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[9] Tr. at 85 (SER307). In fact, commenters had already suggested USDA tneeded to consider the possibility of such regionalization; however, that possibility increases the potential risk of resuming imports from Canada, rather than explaining it away. *See, e.g.*, Cox Declaration at 6 (SER188); comments of Utah State Veterinarian, AR000311 (SER70). In this case, USDA should have found the possibility of a cluster particularly disturbing, since the majority of the meat and much of the live cattle imported from Canada come from Alberta. *See* p. 29, *infra*.

[10] USDA's flip-flops on the issue of imports of beef from cattle 30 months and older demonstrate the arbitrary nature of USDA's qualitative conclusion that the risk from the Final Rule is minimal. USDA first proposed to exclude edible products from cattle that were 30 months of age or older when slaughtered in Canada ("OTM cattle"), indicating that this would minimize the risk of infectious levels of BSE and is accepted internationally by various countries. 68 Fed. Reg. at 62,391, 62,394. In fact, this was considered so important that USDA proposed to allow imports only if the under-30-month cattle were slaughtered in a separate establishment or otherwise avoided contamination or co-mingling with meat from OTM cattle. *Id.* Four months later, USDA published a statement that it now believed--despite the discovery of an additional BSE-infected cow of Canadian origin and without having conducted a new risk assessment--that imports of beef from OTM cattle should be allowed, as they were in the Final Rule. 69 Fed. Reg. at 10635. USDA indicated that additional discoveries of BSE in Canada would not change its position, 70 Fed. Reg. at 514, but shortly after publication of the Final Rule, it suspended imports of beef from OTM cattle to reconsider the risk in light of two additional cases

Remarkably, USDA's brief goes even further than the preamble to the Final Rule, arguing not that the risk is low, but that it is nonexistent: "the Secretary found no reason to believe that cattle subject to importation will have BSE or that they pose any particular risks at all." USDA Br. at 33. Given that we already know, based on very limited testing, of four cases of BSE in Canadian-raised cattle (all of which, USDA asserts, likely were infected with BSE long before 30 months of age), it is this assertion that no imported Canadian cattle will have BSE, not Judge Cebull's conclusion that USDA failed to explain why the risk of introduction of BSE from Canadian imports is acceptable, that is "difficult to fathom." See USDA Br. at 32.[11] This new USDA assertion is also squarely at odds with the Administrative Record, including the preamble to the Final Rule, in which USDA

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of BSE in Canada. 70 Fed. Reg. 12,112 (April 8, 2005); Op. at 15-16 (ER122-23).

[11] USDA also now claims that "it is unclear why or how" its conclusions about acceptable risk "should or could be restated in quantitative form...." USDA Br. at 32. But APHIS' own published procedures for evaluating the animal health status of countries to define conditions under which animals or animal products might be exported to the United States, AR009519-29, state that, while a qualitative risk analysis is generally deemed adequate for regions considered free of certain diseases, regions in which a disease is known to exist due to recent outbreaks are deemed to pose a higher level of risk and have historically been approached quantitatively. AR009525. This is because "[q]uantitative modeling allows assessment of specific risk concerns, testing of assumptions, analysis of attendant uncertainty, and evaluation of the effectiveness of proposed mitigation measures." *Id.*; *see also* Cox Declaration at 4-8, 12 (SER186-190, 194).

acknowledged numerous risks but concluded that they are "low" or "minimal." *See, e.g.*, 70 Fed. Reg. at 479, 516. (In fact, later in its brief USDA denies ever having claimed that "it is 'reasonable to presume that there is no risk of exposure to BSE infectious agents'" under the Final Rule's requirement for SRM removal. USDA Br. at 39.)

USDA asserts that "interlocking safety measures will prevent the risk of introduction and dissemination of BSE," implying that the Harvard-Tuskegee Study and other, unspecified "many studies in the record... provide quantitative risk analysis" that supports that conclusion. *Id.* This suggestion is disingenuous, at best. While USDA assumes its interlocking safety measures will "prevent the risk of introduction...of BSE" into the U.S., the Harvard-Tuskegee study contradicts this very claim by acknowledging its inability to calculate a probability of introduction of BSE because of "the absence of strong evidence about the prevalence of BSE in the Canadian herd, information that would allow us to calculate a probability of introduction...." AR008426 (SER317).

If indeed USDA could have concluded, based on scientific data, that the "risk of introduction and dissemination of BSE" from allowing Canadian imports would be "prevented" under the Final Rule (see USDA Br. at 32), meaning that there would be no risk, then perhaps there would have been no

need for USDA to quantify its "subjective conclusions" about the acceptability of the risk. But that, unfortunately, is not the case. The very scientific study that USDA relies on to assert that cattle under 30 months of age with their tonsils and small intestine removed present no risk for BSE, even if incubating the disease, states: "As the cattle-to-human species barrier is yet unknown (E.C., 1999), no calculation of infectivity risk for man from an estimated onset of detectable infectivity in cattle CNS can be made." AR011914, AR011953. This conclusion is echoed by the Final Report of the Japan - United States BSE Working Group, July 22, 2004 at 4 (AR001621) (SER149), in which USDA recognized that, even in sub-clinical stages of BSE (without outward signs), the BSE infective agent still resides in the animal (USDA assumes most cases are infected at an early age), and the significance of such lower levels of BSE for health of consumers is "unclear." *Id.* The international panel convened by the Secretary of Agriculture to evaluate U.S. BSE safeguards also acknowledged this, in recommending that the U.S. should remove the brain, spinal column, etc. from all cattle 12 months of age or older: "A cutoff of 12 months represents a recognition of the fact that some cattle under 30 months of age may be slaughtered with infectivity present." [12]

[12] AR008026 (SER112). Despite these conclusions of scientific experts

These and other facts justify the District Court's determination that R-CALF likely will be able to show that USDA failed adequately to assess the risks associated with importing Canadian cattle and beef products before it issued the Final Rule and failed to explain to the public why those risks were acceptable. As R-CALF argued during the hearing on the Preliminary Injunction, by USDA's own estimates the Final Rule would only provide a net societal benefit of $11 million per year, hardly a rational basis for reversing 16-year-old protections against importation of BSE and subjecting the U.S. cattle industry and U.S. consumers to unquantified, but definitely non-zero, risks. Transcript at 19 (SER254); *see, e.g.*, Fox article at 57 (SER92); Inter-agency Work Group at AR009303 (SER26).

C. USDA acted without sufficient knowledge of the extent of BSE infection in Canada.

(and, until recently, USDA itself), that the significance of sub-clinical levels of BSE in cattle for human consumers is unknown, USDA now asserts that human exposure is of little concern, because "all the evidence shows that humans need about 10,000 times the level of exposure that cattle do to contract BSE/vCJD. Tr. at 63 (SER296). But that claim is not supported even by the authors of the Harvard Study on which USDA largely relies, who explained that scientific consensus is that this "species barrier" should be considered 1 (i.e., not to exist) for worse-case modeling, with more likely values somewhere between 10 and 10,000, although "it is not at this time possible to quantify the species barrier...." Harvard Study Revised October, 2003, at AR003707 (SER66b).

The District Court made a factual finding, based in part on the declaration of Dr. Cox, an expert in risk assessment and statistics, that USDA's characterization of the incidence of BSE in the Canadian herd as "minimal" or "very low" was not supported by the available data. Op. at 10 (ER117). The fact that four cases of BSE have been discovered in cattle raised in Canada, after testing only about 40,000, was judged to be inconsistent with USDA's assertion that the prevalence of BSE in Canada is very low (and therefore the risk of introducing BSE into the United States is low). *Id.* at 10-11 (ER117-118).

The District Court also reached the logical conclusion, which was also supported by Dr. Cox, that USDA's reactions to additional discoveries of BSE in the Canadian herd, promptly concluding in each case that the additional data would not change USDA's position,[13] suggested USDA was arbitrarily hewing to a preconceived assumption, since "it is not credible that the magnitude of risk does not depend on how large a portion of Canadian cattle are discovered to have BSE."[14] In fact, this conclusion is directly

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[13] *See, e.g.*, SER161, where APHIS Administrator DeHaven declared his mind made up before Canada had even confirmed the details of a new BSE case.

[14] *Id.* at 11 (ER118). Cf. AR009505 (SER161). USDA declarant Linda Ferguson went so far it as to chastise Dr. Cox for even suggesting that USDA should determine the "true prevalence of BSE" in the Canadian herd,

supported by the Harvard-Tuskegee Study on which USDA relies so extensively, since that study found it impossible to assess the probability of introduction of BSE into the U.S. as a result of resuming imports from Canada "[i]n the absence of strong evidence about the prevalence of BSE in the Canadian herd...." AR008426-27 (SER317-318).

USDA's Brief offers a number of illogical, irrelevant, or obfuscatory responses to this finding, none of which, even if credible, rise to the level of demonstrating an abuse of discretion. The suggestion that there may be a cluster of BSE cases in Alberta (USDA Br. at 35) hardly justifies a conclusion that the risk of importing BSE-contaminated cattle or beef is less, given that over 70% of the beef slaughter in federally inspected plants in Canada takes place in Alberta and almost half of the total Canadian cattle population resides in Alberta. *See* AR002529-33 (SER11-15).

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asserting that this information "is not necessary to determine whether risk management policies... are appropriate or need to be changed...." ER70-71. This statement undercuts the credibility of Ms. Ferguson's entire declaration, since Ms. Ferguson authored a June 16, 2003 memorandum, as chair of the APHIS TSE Working Group, which responded to the first discovery of BSE in Canada, stating: "it is too early to know the true prevalence of BSE in Canada. Until the prevalence of BSE in Canada is determined it will be impossible to quantify how much additional risk some of these commodities present to the United States. Once the prevalence of BSE in Canada is determined through additional surveillance, the risk of these commodities can be reassessed and actions taken to either decrease or increase the restrictions." AR009392A (SER56).

USDA's suggestion that the Court should not be concerned about the discoveries of four cases of BSE in Canada in the last two years because none of those cattle could have been imported under the Final Rule, since they are older than 30 months (USDA Br. at 35), ignores the fact that, under the Final Rule as originally issued, meat from those animals could have been shipped to the United States (and even under the amended Final Rule, had they not been identified through outward signs followed by testing, contaminated protein from them could have infected younger Canadian cattle through gaps in the feed ban). Moreover, the amendment to the Final Rule expressly allows the importation of bovine liver from these older cattle. 70 Fed. Reg. at 12113 n. 2.

USDA's claim that these four cases actually demonstrate that the prevalence in Canada is exceedingly low "because all the cows were born before or shortly after the time the feed ban was instituted, thereby removing the only source of BSE transmission in cattle" (USDA Br. at 35-36), is circular and inconsistent with other USDA arguments: If indeed, as USDA asserts in order to explain away these cases despite over seven years of a Canadian feed ban, the BSE incubation period in Canada is likely longer than seven years, then cattle infected with BSE after the August 1997 feed ban would not yet have shown any outward signs of BSE. *See also*

comments of the United States Animal Health Association, AR000653 (SER106) ("there are likely additional cases of BSE in" Canada).

USDA's implication that, despite Dr. Cox's expert opinion, the limited testing for BSE in Canada has been sufficient to determine that the prevalence of BSE in Canada is "exceedingly low" because Canada has exceeded O.I.E. guidelines for surveillance testing (*id.*) conveniently ignores the fact that those guidelines are for testing to determine whether BSE is present in a country (which it obviously is in Canada) and not to determine the prevalence where BSE is known to exist. *Cf.* AR010077 *with* AR010060 (SER181, 164). Other expert commenters supported Dr. Cox's conclusion that testing has been inadequate to determine the extent of Canada's BSE problem: "This statement [prevalence will be lower] does not take into account that the level of determined prevalence is dependent on the quality and level of surveillance. While a country may state they have a low prevalence, their surveillance level may be inadequate to accurately measure that." AR001258 (SER101) (Arizona State comments). USDA's TSE Working Group member Gary Svetlik, DVM also reinforces this caution: "The OIE recommendation mentioned above are for countries which have not diagnosed a case of BSE in native cattle; therefore, more surveillance should be required." AR000392 (SER79).

USDA's insistence that the prevalence of BSE in Canada is extremely low, as well as its insistence that the prevalence does not even affect the risk of introduction of BSE into United States, is plainly just wishful thinking and inconsistent with the facts, including the statements of USDA's own internal and external experts. There is no basis for holding that these factual conclusions by the District Court constituted an abuse of discretion.

D. USDA's reliance on "feed bans" as virtually eliminating BSE risk was not justified by the record.

1. USDA's explanation of its assumption that Canada's feed ban minimizes the risk of BSE was unsupported by the facts and internally inconsistent.

USDA claims in its brief that "feed bans that prevent the recycling of the infective agent have been overwhelmingly successful even in Europe were exposure is assumed to be the highest. [70 Fed. Reg.] at 463." USDA Br. at 23. In fact, the cited Federal Register page contains no assertion that feed bans have been "overwhelmingly successful," but only that they have been "effective" in reducing BSE.[15] Nor could it: data in the preamble to the Final Rule and elsewhere in the administrative record show that tens of thousands of cattle found to be infected with BSE were born in the UK years

[15] Likewise, the cited Federal Register pages do not support the claim on page 23 of USDA's brief that risk mitigation measures adopted by FDA and FSIS "ensure" that importation of a BSE-infected Canadian animal "would not result in dissemination of the disease. Id. at 465-66."

after the UK implemented a feed ban comparable to that in place in Canada and the U.S. *See* graphs from the record presented at the preliminary injunction hearing (SER313); *see also* Fox, et al., at 49-50, 56, AR001569, 001574 (SER84-85, 91) (over 44,000 cases of BSE confirmed in cattle born after the feed ban). Other European countries have had a similar experience, despite the fact that their feed bans are more stringent than in the U.S. and Canada. Fox at 52, 56, AR001570, 001574 (SER87, 91); *see also* comments of USDA Veterinarian Gary Svetlik, AR000388 (SER75) ("BSE cases continue to be diagnosed in other parts of the world in animals well past the implementation of feed bans."); Inter-agency Working Group at AR009302 (SER25).

Thus, what the UK and European experience actually demonstrates is that a feed ban, especially a limited feed ban as exists in Canada and the U.S., reduces but does not eliminate the risk of BSE transmission; despite very extensive efforts overseas to control BSE, hundreds of new cases of BSE are being discovered every year.

As recently as 2002, USDA itself implicitly recognized the limitations of its 1997 feed ban, insisting that a ban on imports of live cattle and meat from countries with BSE was necessary because, despite the U.S. feed ban, "BSE could become established in the United States if materials carrying the

BSE agent, such as certain meat, animal products, and animal byproducts from ruminants, are imported into United States and are fed to ruminants in the United States" and "BSE could also become established in the United States if ruminants with BSE are imported into the United States." 66 Fed. Reg. 52,483 Oct. 16, 2001("emergency" interim rule banning imports from Japan, affirmed at 67 Fed. Reg. 8181 (Feb. 22, 2002)).

USDA's claim here of the "overwhelming success" of feed bans cannot overcome the District Court's factual finding that "USDA's claims that there is minimal risk of transmission of BSE within the United States and that Canadian cattle under 30 months of age should be BSE-free, based on the assumed effectiveness of the Canadian and U.S. feed bans[,] are inconsistent with the facts available to the USDA" and that "USDA based the Final Rule largely on this assumed effectiveness and failed to justify this assumption in light of all the contrary evidence...." Op. at 14 (ER121).

R-CALF explained, in its briefs and at the preliminary injunction hearing, that USDA acted irrationally when it rejected international consensus that a feed ban should be in place and effective for at least eight years for a country to be considered "minimal risk," and that USDA had provided inconsistent explanations of the "incubation time" for BSE and its

implications for USDA's conclusions about the adequacy of Canada's feed ban. Transcript at 29-31, (SER264-66); Cox Declaration at 7 (SER189).

USDA rejected the international guidelines of the O.I.E., requiring that a country have had in place and been enforcing an effective ban on feeding ruminant protein to ruminants for at least eight years, claiming that time period "may be conservative," since the mean incubation period for BSE was estimated at 4.2 years, with 7.5 years representing the 97.5th percentile. 70 Fed. Reg. at 470. USDA also asserted that, "because the two BSE-infected animals were born before the feed ban, there is no evidence to suggest that the feed ban is ineffective." 70 Fed. Reg. at 515.

R-CALF then pointed out that USDA's assumption that Canada's feed ban has been in place long enough to protect against BSE was inconsistent with the fact that one of the cows found to have BSE in Alberta at the beginning of 2005 was born seven months after the feed ban, and all of the native cattle found with BSE in Canada, if they in fact were infected before the 1997 feed ban as USDA assumed, first showed signs of BSE long after the 4.2 years that USDA asserts is the average incubation period for BSE in Canada, and the two latest cases would have had to have been incubating BSE for longer than 95% of cattle infected with BSE. 70 Fed. Reg. at 470; Cox Declaration at 7, (SER189).

Faced with these illogical inconsistencies, USDA then asserted that, despite what it had said previously in justifying its claim that 7 years of the Canadian feed ban was sufficient (at 70 Fed. Reg. 470), the typical incubation period in Canada is likely much longer than 4.2 years (more like 7-8 years). USDA Opposition at 13; *see* Transcript at 29-31, 59-61(SER264-266, 292-94). Similarly, USDA's attempt to explain away the fact that the latest BSE case in Canada was born seven months after the effective date of the Canadian feed ban was to assume that cow was exposed at a young age to prohibited feed that had been manufactured prior to the feed ban but was still available for feeding. As the District Court recognized, this simply further undercuts USDA's assertion that Canada has had an effective feed ban for seven-plus years. Op. at 13 (ER120).

These internally inconsistent, flip-flopping statements by USDA in a desperate attempt to rationalize its assumptions and support its preconceived goal are not deserving of deference and render the agency's action arbitrary and capricious, and accordingly the District Court properly recognized that R-CALF had a substantial likelihood of prevailing on the merits.[16]

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[16] The District Court also noted that setting a risk-minimization criterion that a country's feed ban must have been in place only as long as the expected maximum incubation time for BSE "appears to be arbitrary and capricious and inconsistent with the USDA's responsibility to protect

2. R-CALF showed it was arbitrary and capricious for USDA to rely on the Canadian feed ban, since it does not ban bovine blood or poultry litter or plate waste from cattle feed, nor does it address cross-contamination.

Both Canada and the United States allow bovine blood to be used in cattle feed. 70 Fed. Reg. at 491. USDA has acknowledged the possibility of transmission of BSE through blood and has refused to allow importation of blood products from Canada (*see e.g.*, 70 Fed. Reg. at 502), and there is growing recognition that BSE can be transmitted in humans and other animals through blood. *See* AR009308 (SER3); AR001560 (SER141). The Food and Drug Administration (FDA) has recognized a need to upgrade current feed regulations to eliminate use of mammalian blood, but it has not yet taken that action. *See* 69 Fed. Reg. 42,288, 42,292-93 (July 14, 2004). TSE Working Group, AR9392C (SER58).

Similarly, USDA and FDA have acknowledged a need to keep poultry litter and plate waste (poultry feed that is spilled during feeding) (herein,

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American cattle and consumers." Op. at 13 (ER120). USDA's response, that Canada has implemented other mitigation measures (USDA Br. at 38) does nothing to change the fact that, under USDA's own assumptions, even if the Canadian feed ban is effective there may still be Canadian cattle infected before or around the effective date of that feed ban. And USDA cannot claim "overlapping" layers of protection if it is also claiming that some of the BSE mitigation measures substitute for sufficient passage of time under an adequate feed ban.

"poultry waste") out of cattle feed, since rendered bovine protein is used in poultry feed, allowing a path for recycling contaminated bovine proteins into cattle feed. Numerous commenters pointed out that this practice allows for direct re-feeding of contaminated bovine protein to cattle, and it therefore has been banned in other countries (after a less-restrictive ban proved inadequate). In fact, USDA's own TSE Working Group recommended eliminating this loophole soon after the first Canadian BSE case was discovered. AR009392C (SER58).

Numerous experts also commented on the practical difficulties of avoiding cross-feeding on the farm (allowing cattle to eat pig feed, for example) and cross-contamination in feed mills that the U.S. allows to process both ruminant feed and non-ruminant feed (which can contain ruminant protein).[17] Given the tiny amount of infected tissue that can cause infection when consumed (the size of a grain of sand), the risk that BSE will

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[17] *See, e.g.*, AR000388 (SER75)("cross contamination and lack of farm level compliance represents a risk and was one of the reasons BSE was diagnosed in some other countries"), AR000389 (SER76)(cross-contamination was source of BSE cases in Europe), AR000391(SER78)(noncompliance with Canadian feed ban at one of the suspected farms with BSE); AR000371 (SER72)(European Commission noting "experience within the EU has shown that implementation of a ruminant to ruminant feed ban is very difficult to achieve due to cross contamination or accidental feeding on farms with different species...." *See also* report of the Secretary's International Review Team at AR008029-30 (SER115-16).

spread to the U.S. herd if infected cattle are introduced into the U.S. is real and unavoidable, but USDA has not even taken the same steps to strengthen the feed ban as other countries have and as USDA's own experts urged. *See* TSE Working Group AR009392C-D (SER58-59); European Union Scientific Steering Committee for BSE, AR011791 (SER6) (as long as feeding of ruminant protein "to other farm animals is legally possible, cross-contamination of cattle feed with animal (ruminant) protein cannot be eliminated....It should be clear that any cross-contamination of cattle feed with MMBM, even well below 0.5%, represents a risk of transmitting the disease.")

USDA's response to comments that the feed ban is inadequate was simply to acknowledge that these gaps in the feed ban exist and that USDA and FDA are considering what improvements to the feed ban are needed. 70 Fed. Reg. at 466, 504. As the District Court correctly recognized, there is a substantial likelihood that R-CALF will succeed on its claim that it was arbitrary and capricious for USDA nevertheless to assume that the Canadian feed ban is effective and sufficient.[18] Consistent with its long-standing

[18] Similarly, the District Court correctly apprehended the irrationality of USDA's refusal to even consider prohibiting imports of or requiring testing of cattle under 30 months of age, in light of the facts that, *inter alia*, of the relatively few cattle found in Japan with BSE, at least two were substantially

policy that "strict import requirements are justified to control even very low-probability risks of introducing BSE" (56 Fed. Reg. at 63,867), USDA should have acted to mitigate these risks of an inadequate feed ban. Instead, the agency simply punted on the issue, ignoring the admonition of the Secretary's own inter-agency work group, that imports of apparently healthy BSE-infected cattle which then are rendered and eventually enter the ruminant food chain are one of the biggest risks of introduction of BSE into the U.S. herd. AR009303 (SER26).

E. USDA's reliance on SRM removal to eliminate risk to humans was not justified by the record.

The District Court reviewed the "extensive comments and numerous reports on the latest scientific research" that R-CALF had submitted to USDA, "which indicate that it is no longer reasonable to presume that there is no risk of exposure to BSE infectious agents once an SRM removal requirement is in place." Op. at 15 (ER122); see also Cox Declaration at 8-9 (SER190-91). Accordingly, the District Court concluded that R-CALF likely could show that "USDA's failure to explain clearly why these concerns do not undercut its reliance on SRM removal requirements for the

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younger than 30 months and would not have been discovered but for testing. *See* AR001563 (SER144).

protection of public health from Canadian imports" was arbitrary and capricious. *Id.*

The only SRMs required to be removed from Canadian cattle slaughtered in Canada for export to the U.S. or slaughtered in the U.S. under the Final Rule, as modified March 11, 2005, are the tonsils and the small intestine.[19] This is based on the assumption that these tissues are likely to carry the highest level of infectivity in cattle under 30 months of age. See 70 Fed. Reg. at 497-98. But USDA itself recently acknowledged that the "distribution and amount of the BSE agent in cattle infected with BSE is not known with certainty," 69 Fed. Reg. 1861, 1863 (Jan. 12, 2004). USDA also acknowledged that the BSE infectious agent "in younger animals is unlikely to be detected using current testing methods" and that "at present any relationship of such undetectable levels of abnormal prion protein in CNS tissues to consumers' risk is unclear." Final Report of the Japan-United States BSE Working Group, July 22, 2004 at 4 (AR001621) (SER159).

USDA's only response is to assert that the District Court's concern was misplaced because USDA never claimed that SRM removal removes

[19] The tongue may be used for food, after the tonsils are removed, even though USDA had before it scientific data indicating that BSE infection may also travel to the tongue (AR001650) and USDA apparently conducted no studies to assess the potential for contamination of the tongue with tonsil material during slaughter and processing.

the risk of human exposure to BSE infectious agents. USDA Br. at 39. This is another example of the revisionist history in USDA's brief. In the preamble to the Final Rule, USDA concluded that there was no need to exclude Canadian cattle most likely to have BSE, those 30 months and older, "because the removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that pass both ante-mortem and post-mortem inspections (i.e., apparently healthy cattle)...." 70 Fed. Reg. at 465; *see also* Ferguson Declaration at 7 (ER74) (introduction of the BSE agent into the U.S. "would be extremely unlikely... to result in human exposure to the BSE agent, based on the safeguards that have been established...").

The only safeguards related to human exposure established through the Final Rule is that the tonsils and small intestine of Canadian cattle will be removed. Under the Final Rule, the brains, spinal cord, and bones of Canadian cattle up to 30 months of age can enter the human food chain. The District Court's judgment that R-CALF likely will be able to show, through scientific studies in the record and USDA's own admissions, that USDA lacked a sufficient basis for its assertion that human exposure to BSE is extremely unlikely under these circumstances was not in error.

F. The Final Rule arbitrarily leaves open a route of BSE exposure through imports of pregnant cattle.

The District Court found a logical inconsistency between USDA's recognition that there is some risk of BSE being transmitted to offspring, as well as USDA's conclusion that there is risk that BSE infection can be carried by fetal blood serum, versus USDA's failure to provide protections in the Final Rule against dissemination of BSE in United States through importation of pregnant cattle from Canada. Op. at 16 (ER123). Given the millions of Canadian cattle expected to be imported under the Final Rule, the District Court reasonably concluded that, absent pregnancy checking as a condition of entry into the U.S., a percentage of the heifers imported from Canada would be pregnant, and thus would present a risk of dissemination of BSE through BSE-infected calves and fetal blood serum. *Id.*

USDA's critique of the District Court's conclusions misses the mark. USDA claims that the District Court ignored provisions of the Final Rule designed to assure that cattle will be imported only for slaughter or for feeding prior to slaughter, and cannot be diverted to breeding uses. USDA Br. at 40-41. But the District Court's findings addressed the likelihood that heifers would already be pregnant when imported into the United States, not

that they would be diverted unlawfully for breeding, and the District Court found USDA's failure to require that calves born by imported Canadian cattle be euthanized meant that those "calves could become a vector for BSE infection in the U.S." Op. at 16 (ER123).

In the past, USDA (like other countries) has recognized the possibility that BSE can be transmitted to offspring and has euthanized offspring of the one (Canadian-born) cow found to have BSE in the U.S. *See* 70 Fed. Reg. at 530; *see also* 70 Fed. Reg. at 515 (O.I.E. guidelines require that offspring of animals in the same birth cohort as BSE-infected cattle be excluded from food and feed chains). The District Court reasonably concluded that R-CALF likely could show it was arbitrary and capricious in light of those facts for USDA to leave unregulated calves born of imported Canadian heifers. USDA's assertion that the risk is "not sufficient to sustain an epidemic" (USDA Br. at 41-42) is hardly comforting, especially in light of the government's admission that " the economic consequences from even one confirmed case of BSE in the United States could easily exceed the costs incurred thus far in the United Kingdom...."[20]

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[20] PL107-9 Interagency Working Group Report, AR009304 (SER27). USDA also completely misconstrues the District Court's conclusions with respect to fetal blood serum. USDA Br. at 42. The District Court did not hold that USDA wrongfully failed to prohibit imports of fetal blood serum,

G. USDA's response to comments urging mandatory BSE testing for Canadian cattle was illogical and insufficient.

The Administrative Procedure Act requires that an agency provide a cogent in response to important public comments on a proposed rule. Numerous commenters urged USDA to require testing for BSE when Canadian cattle are slaughtered in the U.S. or are slaughtered in Canada to be imported to the U.S. They pointed out that such testing could identify BSE-infected cattle that would not otherwise be detected, keeping infected tissue out of the food supply and the feed supply. They also pointed out that testing could help address fears of foreign and domestic consumers that the U.S. meat supply will now carry a higher risk of BSE infection.

USDA did not ignore these comments altogether, but its response was illogical and inadequate. USDA's stated reasons for not requiring testing essentially come down to one point: that often cattle without outward signs of BSE infection could be infected and still not be identified with the

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but rather noted that that prohibition was inconsistent with USDA's failure to require pregnancy checking at the border or otherwise to regulate imports of pregnant Canadian heifers and any calves they may bear in the U.S. Op. at 16-17 (ER123-24).

available post-mortem BSE tests.[21] 70 Fed. Reg. at 475, 534; USDA Br. at 42-43.

USDA acknowledged that the standard BSE screening test can identify BSE infection months before the animal has outward signs of BSE.[22] USDA rejected mandatory testing because it cannot detect BSE infection until the disease has progressed fairly far. 70 Fed. Reg. at 475. But the fact that it cannot detect all cases of BSE does not mean testing has no value, since it would detect some BSE cases that would otherwise go undetected. R-CALF provided the District Court with an article in which Dr. Stanley Pruisner, who won the Nobel Prize for discovering prions, pointed out that neither of the under-30-month-old cattle found with BSE in Japan would have been identified without Japan's policy of testing all

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[21] The Declaration of USDA economist Frank Fillo (ER86, 97) offered additional arguments against testing, primarily that it would be too costly. Those arguments were not the basis USDA provided in the preamble to the Final Rule or elsewhere in the Administrative Record for its refusal to require BSE testing. The District Court was not required or permitted to consider such post-*hoc* rationalizations. *See, e.g., Motor Vehicle Mfrs.*, 463 U.S. at 50.

[22] 70 Fed. Reg. at 475. In fact, the Canadian-raised cow found to have BSE in Washington State would never have been tested for BSE if it had been screened for symptoms of BSE only. *See* Bullard Declaration (ER53). Of course, mandatory testing could also catch cases where inspectors failed to notice the somewhat-subjective signs of neurological disorder (*e.g.* changes in temperament, abnormal posture, and lack of coordination, *see* 62 Fed. Reg. at 65,748) in the hundreds or thousands of cattle passing through a slaughterhouse each day.

animals at slaughter, as "[n]either animal showed outward signs of neurological dysfunction." AR012125.[23] Thus, the District Court found, on the evidence before it, that USDA's failure to give careful consideration to the benefits (and costs) of mandatory testing, or at least its failure to explain to the public why the benefits of potentially catching some BSE-infected carcasses that would otherwise enter the human food and animal feed chains do not justify mandatory testing, likely was arbitrary and capricious and in violation of the Administrative Procedure Act. Op. at 17 (ER124). A test that produces "false negatives" (i.e., misses many infected animals) is still better than no test at all, especially in light of the severe consequences if even one BSE-infected Canadian animal is missed. *See id.* USDA's brief certainly does nothing to show that the District Court's factual conclusions in that regard constituted an abuse of discretion.

[23] *See also* EU "Report on the assessment of the Geographical BSE-risk of Canada" at 5 (AR011790, SER5), concluding that data from Switzerland and the UK indicate that it is likely that testing only "symptomatic BSE-suspects, will not detect more than half or one third of all clinical [i.e., capable of detection] cases, or even fewer."

III. The District Court's finding that USDA failed to give serious consideration to regulatory options that would have lessened the impact of the Final Rule on small businesses was not clearly erroneous.

The Regulatory Flexibility Act, 5 U.S.C. §§ 601-612 ("RFA"), requires an agency to carefully consider the economic impact a rule will have on small entities, by conducting a final regulatory flexibility analysis that describes the steps the agency has taken to minimize the significant economic impact on small entities, and explains why the agency rejected significant alternatives that would reduce the impact on small businesses. 5 U.S.C. § 604(a)(5). The RFA does not mandate specific substantive measures, but it does require the agency to give explicit consideration to less onerous options, and a reviewing court should determine whether an agency made "a reasonable, good-faith effort to canvass major options and weigh their probable effect." *Associated Fisheries, Inc. v. Daley,* 127 F.3d 104, 114 (1st Cir. 1997).

USDA admits that the Final Rule will primarily affect small businesses. 70 Fed. Reg. at 543. Many ranchers, including most R-CALF members, are small businesses within the meaning of the RFA. *See* Bullard Declaration (ER47). USDA estimates that the Final Rule has a present-value

cost of close to $3 billion for U.S. cattle producers like R-CALF's members. 70 Fed. Reg. at 539.

The District Court found that USDA likely did not comply with its RFA obligation to "make a good-faith effort to assess all significant alternatives," because it did not give serious consideration to how two options suggested by commenters--labeling of Canadian product and allowing U.S. slaughterhouses to test Canadian cattle for BSE before they are processed-- could have mitigated this severe impact on small businesses. USDA did not consider the mitigation of adverse effects of the Final Rule on small businesses. Op. at 22-24 (ER129-31); cf. 70 Fed. Reg. at 542-43. Either of those options might have substantially mitigated the adverse economic effects of the Final Rule. *See, e.g.*, VanSickle Declaration at 7-8 (SER202-203); Comments of Washington Cattlemen's Association, AR001025 (SER104).

Far from showing that the District Court abused its discretion in determining that USDA failed to comply with the RFA, USDA's brief simply repeats USDA's non-responsive responses to R-CALF's arguments, and then acts as if the District Court ignored USDA's responses. *Cf.* USDA Brief at 44-45 *with* Op. at SER129-31. USDA does not dispute that it had an obligation under the Regulatory Flexibility Act to consider alternatives to the

Final Rule that would mitigate the economic impact of the Final Rule on small businesses, such as R-CALF's members. Instead, USDA offers illogical or unsupported reasons for not considering obvious mitigation measures, suggested to the agency in comments, as required by the Regulatory Flexibility Act.

First, USDA asserts that the District Court wrongly "held that USDA 'did not consider' that the rule's effect on small businesses could have been mitigated by requiring Canadian cattle or beef products to be labeled with their country of origin...." USDA Br. at 44. But USDA's own economist told the District Court that "APHIS did not consider COOL [country of origin labeling] as a mitigating measure under this rule...."[24]

USDA's stated basis for asserting that a requirement for labeling of Canadian-origin meat would not mitigate economic impacts of resuming Canadian imports is unsupported and illogical. USDA gives two responses to the obvious fact that labeling would allow consumers to assure themselves, if they chose, that they were not being exposed to meat products from a country where BSE is known to exist, thereby mitigating the adverse

[24] Fillo Declaration at ¶12 (ER96). (Fillo's declaration went on to offer post-*hoc*, extra-record rationalizations why, if APHIS had considered labeling as a mitigation measure, it would have rejected it. The District Court properly ignored these. *See, e.g., Motor Vehicle Mfrs.*, 463 U.S. at 50.)

effect on domestic and foreign consumer demand for U.S. beef that even USDA acknowledges is likely to result from resuming Canadian imports. First, USDA says that it will be issuing a country-of-origin labeling program in September 2006, and it "does not consider it necessary to delay implementation of" the Canadian BSE rule until then. 70 Fed. Reg. at 533. USDA does not contest R-CALF's assertion that USDA has authority now to impose a country-of-origin labeling requirement with respect to Canadian beef, and so saying that it plans to do so two years in the future is hardly a reasoned consideration of alternatives as the Regulatory Flexibility Act requires.[25]

Then USDA offers a curious rationale for not seriously considering the labeling option: it is not a food safety or an animal health measure, but rather a measure "to provide consumers with additional information on which to base their purchasing decisions." Fillo Declaration ¶12, ER96. That statement is no reason at all why USDA should not have considered providing consumers with "additional information" on which to base their decision whether to purchase Canadian-origin meat in light of the discoveries of BSE in the Canadian herd, when doing so could blunt the

[25] At the preliminary injunction hearing, counsel for USDA mused that the agency might not have this authority, but that claim was not raised in USDA's briefs nor in the preamble to the Final Rule.

impact of allowing imports from a country with BSE, especially if additional cases of BSE are found in Canada or in Canadian cattle that have entered the United States. Op. at 23-24 (ER130-31); AR001025 (SER104).

With respect to the potential value of voluntary testing for BSE as a means to mitigate the adverse financial impacts of the Final Rule, USDA again asserts that the District Court incorrectly concluded the USDA did not assess this option as a means of mitigating the impact on small businesses. USDA Br. at 45. But USDA's own discussion of its RFA analysis is devoid of any such consideration.[26] *See* 70 Fed. Reg. at 543 (ER267); *see also* USDA, Economic Analysis (AR8138).

The notion that consumer demand will be adversely affected by imports from a country known to have BSE, and especially by the discovery of additional cases of BSE, which are likely in the Canadian herd, is not simply speculation on the part of Dr. VanSickle. There is no need to speculate: the discovery of a BSE-infected cow of Canadian origin in the

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[26] USDA did consider comments, unrelated to the impact on small business, that USDA should allow voluntary testing. Its conclusion that *additional*, voluntary testing of cattle for BSE would not be consistent with USDA's mandate "to maintain domestic and international confidence in U.S. cattle and beef products" (70 Fed. Reg. at 534 (ER258)) is illogical, as the District Court concluded. Op. at 23-24 (ER130-31). An agency decision that is not, at a minimum, based on "reasonable extrapolations from some available evidence" is arbitrary and capricious. *Natural Resources Defense Council v. Thomas*, 805 F.2d 410, 432 (D.C. Cir. 1986).

United States caused dozens of countries to close their borders to U.S. meat and imposed many millions of dollars of losses on the U.S. livestock industry. VanSickle Declaration at 2, 5 (SER197, 200); Bullard Declaration at 3-4 (ER48-49); Fox, *et al.*, "Risks and Implications of Bovine Spongiform Encephalopathy for the United States: Insights from other Countries," 29 *Food Policy* 45 (2004) (AR1565) (SER80) ("A single case of BSE would have serious consequences for the US beef industry."); comments of Chief Animal Health Official of Arizona (AR001257-58) (SER100-101) ("The economic analysis accompanying the proposed rule does not estimate the impact on the U.S. beef cattle industry as a result of trading partner discomfort with the lessening of restrictions on importation of ruminants in their products from Canada. USDA must...take this significant impact into consideration."). This is not speculation, but rather is based on experience in the United States and in other countries.[27]

[27] Most countries in Europe as well as Japan test a large portion of the cattle they slaughter for BSE. AR1619 (SER147); SER312.

IV. The District Court's finding that there was a likelihood R-CALF would succeed in showing USDA failed to comply with NEPA was not clearly erroneous.

A. R-CALF had standing to raise NEPA issues.

USDA argues that R-CALF has failed to demonstrate that its injuries fall within the "zone of interests" that the National Environmental Policy Act ("NEPA") was designed to protect. USDA Brief at 47-48. USDA relies almost entirely on cases that predate *Bennett v. Spear*, 520 U.S. 154, 162-63 (1997), in which the Supreme Court restricted broad applications of the zone of interests test (holding that a group of ranchers could pursue Endangered Species Act claim that would be to their financial benefit). In any event, the zone of interests argument is irrelevant because R-CALF has adequately alleged environmental harm in addition to economic harm. *See* Complaint at 3, ¶2 (ER3). The fact that R-CALF's members also suffer an economic injury does not preclude it from asserting a NEPA challenge. *See Presidio Golf Club v. National Park Serv.*, 155 F.3d 1153, 1158 (9th Cir. 1998); *see also Friends of the Boundary Waters Wilderness v. Dombeck*, 164 F.3d 1115, 1127 (8th Cir. 1999) (court need not consider whether plaintiffs were more concerned with economics than the welfare of the physical environment).

The zone of interests test is "not a demanding one," *Chief Probation Officers of Cal. v. Shalala*, 118 F.3d 1327, 1331 n.2 (9th Cir. 1997), and a rough correspondence of interests is sufficient. Some of the types of injury that R-CALF members alleged are even the same types of injury that USDA discusses in the Final Environmental Assessment (ER278).[28]

B. R-CALF demonstrated a likelihood of success on its NEPA claim.

R-CALF demonstrated that USDA had failed entirely to consider significant adverse environmental impacts that would result from the Final Rule in terms of increased truck traffic and increased environmental releases at feedlots. R-CALF showed that, even by USDA's estimation, the Final Rule would result in a flood of close to 2 million head of cattle from Canada into the U.S. in 2005, which would translate into about 35,000 truck round-trips between Canadian ranches and feedlots to feedlots and slaughter facilities in the U.S. *See* 70 Fed. Reg. at 540; Bullard Declaration (ER53-54). R-CALF also pointed out that this Court recently concluded that allowing 34,000 Mexican trucks to cross the border would have a significant environmental impact. *Public Citizen v. United States Dep't Transp.*, 316

[28] USDA improperly raises for the first time on appeal its claim that R-CALF failed to complain of environmental impacts in comments. In any case, the need for an environmental impact statement in fact was discussed in comments on the proposed rule. AR005065 (SER118).

F.3d 1002, 1021 (9th Cir. 2003), *rev'd on other grounds, United States Dep't Transp. v. Public Citizen*, 124 S.Ct. 2204 (June 7, 2004). Consistent with the Ninth Circuit's decision on that issue, the impact of transporting two million head of cattle from farms in Canada to feedlots and slaughterhouses in the United States should have been assessed.[29]

USDA claims its failure to assess these environmental impacts is moot in light of its issuance, after the Preliminary Injunction, of a Finding of No Significant Environmental Impact. USDA Br. at 51. But the purpose of NEPA is to assess environmental impacts before agency decisionmaking, not months afterwards. *See, e.g., Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1356 (9th Cir. 1994); see also *Lanthan v. Brinegar*, 506 F.2d 677, 693 (9th Cir. 1974) ("grudging, pro forma compliance will not do").[30]

V. The District Court's assessment of irreparable injury and the balance of hardships was not clearly erroneous.

This Court has described several sets of criteria that, if satisfied, justify issuance of a preliminary injunction. Two of those formulas are that the plaintiff demonstrates a combination of "*probable* success on the merits

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[29] Unlike the *Public Citizen* case, here USDA was not obliged to let Canadian cattle across the border regardless of environmental impact. *Cf.* 124 S.Ct. at 2214-15 *with* USDA Br. at 20-21.

[30] This is certainly not a case where there were simply "two minor procedural defects in the rulemaking process." *Safari Aviation v. Garvey*, 300 F.3d 1144, 1152 (9th Cir. 2002).

and the *possibility* of irreparable harm," or that there is less likelihood of success on the merits but the balance of hardships tips sharply in the plaintiff's favor. *Earth Island Inst.*, 351 F.3d at 1298.

USDA disagrees with the District Court's assessment of the relative harms, but it cannot show that the District Court's conclusions constituted an abuse of discretion. USDA itself estimated that the Final Rule would cost R-CALF members and other producers as much as $2.3 billion, a loss for which they would have no remedy at law. 70 Fed. Reg. at 542. That alone constitutes a huge irreparable harm which USDA believes is at least possible, if not likely. That, combined with the Court's conclusions about the likelihood of R-CALF's success on some or all of its merits claims, is sufficient under this Court's precedent to support issuance of a preliminary injunction. Even if the claimed adverse impacts others are suffering as a result of the continuation of the *status quo* under the preliminary injunction were accurate, they would not preclude issuance of a preliminary injunction under those circumstances.[31]

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[31] "As to the harm to the meat packing industry, Congress has unequivocally determined that public health is to take precedence over commercial interests in this matter." *Cmty. Nutrition Inst. v. Butz*, 420 F.Supp. 751, 757 (D.D.C. 1976). The claimed harms from a shortage of cattle in the U.S. during the few months the preliminary injunction will be in effect are not credible, in any event: USDA projects imports of about 650,000 head of fed cattle and

Beyond this, though, the Court recognized the risk of catastrophic effects on the U.S. cattle market if another BSE-positive animal from Canada were discovered in the United States, or if more cases of BSE were discovered in Canada after large imports have Canadian cattle and beef had occurred under the Final Rule. The Court noted the effect that the discovery of a single case of BSE in Washington State (in a cow raised in Alberta) had had on the U.S. beef industry (Op. at 2-3, 25; ER109-110, 132) and recognized that, once Canadian cattle enter the U.S., the harm or potential harm could not later be avoided.[32] Op. at 25-26 (ER132-33). In this way, this case presents the same type of injury that can never be undone that this Court found to tip the balance in favor of injunctive relief in *Neighbors of Cuddy Mountain v. U.S. Forest Serv.*, 137 F.3d 1372, 1382 (9th Cir. 1998) (logging of old-growth forests). And of course, because BSE and vCJD have no known cure, any infection in the United States resulting from imports have higher-risk Canadian cattle would be an irreparable injury.

145,000 head of feeder cattle in the first year, or less than one percent of the U.S. herd size of 95 million. *Cf.* Fillo Declaration (ER91) *with* USDA Economic Analysis, AR008173 (SER160).

[32] Op. at 25-26 (ER132-33). There was ample support for these conclusions in the Administrative Record. *See* pp. 46-54, *supra*; Comments of the Commissioner of the Utah Dept. of Agriculture and Food, AR000311 (SER70) ("The risk to the American beef grower and the established gene pool in his herd, is immense. The potential devastation to a rural America and to American producers is simply too large a risk.").

"Faced with ... a conflict between financial concerns and preventable human suffering, [the court has] little difficulty concluding that the balance of hardships tips decidedly in plaintiffs' favor." *Lopez v. Heckler,* 713 F.2d 1432, 1437 (9th Cir. 1983).

USDA offers a circular, boot-strap argument: because the District Court erred in concluding that R-CALF may succeed on its claim that the Final Rule presents an unacceptable risk, the District Court wrongly assumed that there would be some injury resulting from the Final Rule. USDA Br. at 58-60. But this also means the converse is true: unless the District Court abused its discretion when it found a likelihood of success on the merits, then its conclusion concerning the possibility of irreparable harm was not an abuse of discretion, either. Regardless, USDA itself has described the multi-billion-dollar adverse impact the Final Rule will have on R-CALF's members and other producers, even if it does not reduce domestic or foreign demand for beef and does not result in any BSE infection.[33] And the District Court found, with ample support in the record as well as in common sense, that resuming imports of Canadian cattle and expanding

[33] USDA also estimated that, if accepting cattle and meat from a country with BSE caused major trading partners to avoid U.S. beef, the cost would be an additional $2.5-3 billion. USDA Economic Analysis—Proposed Rule, AR001727 (SER68).

imports of Canadian beef on the heels of the discovery of two additional cases of BSE in Canada would necessarily reduce consumer confidence in the U.S. meat supply.[34] The Federal Inter-agency Working Group agrees, finding that "the economic consequences from even one confirmed case of BSE in the United States could easily exceed the costs incurred thus far in the United Kingdom..." AR009304 (SER27).

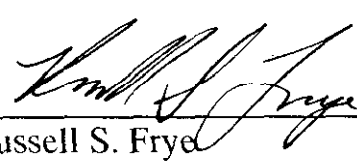
These are huge, irreversible adverse impacts. The District Court did not abuse its discretion when it concluded that the risks presented by the Final Rule justified enjoining it until a hearing on the merits.

CONCLUSION

For the reasons set forth above, R-CALF respectfully requests that this Court deny USDA's appeal of the District Court's issuance of the Preliminary Injunction.

Dated: May 26, 2005

Respectfully submitted,



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[34] Op. at 24 (ER131); *see* pp. 52-53, 56-58, *supra*.

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CERTIFICATE OF COMPLIANCE PURSUANT TO FED. R. APP. P. 32(A)(7)(C) AND CIRCUIT RULE 32-1

I certify that:

__X__ 1. Pursuant to Fed. R. App. P. 32 (a)(7)(C) and Ninth Circuit Rule 32-1, the attached opening/answering/reply/cross-appeal brief is

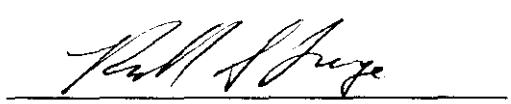
__X__ Proportionately spaced, has a typeface of 14 points or more and contains _13,931__ words (opening, answering, and the second and third briefs filed in cross-appeals must not exceed 14,000 words; reply briefs must not exceed 7,000 words),

Or is

____ Monospaced, has 10.5 or fewer characters per inch and contains _____ words or _____ lines of text (opening, answering, and the second and third briefs filed in cross-appeals must not exceed 14,000 words or 1,300 lines of text; reply briefs must not exceed 7,000 words or 650 lines of text).

Dated this 26th day of May 2005.

Respectfully Submitted,



Russell S. Frye

STATEMENT OF RELATED CASES

R-CALF is aware of one pending case that is related to the instant case: Ninth Circuit Docket No. 05-35214, which is the National Meat Association's interlocutory appeal of the District Court's February 24, 2005 denial of its motion to intervene and the District Court's March 2, 2005 issuance of a preliminary injunction in *Ranchers Cattlemen Legal Action Fund United Stockgrowers of America v. U.S. Dept. of Agriculture*, D. Mont. No. CV-05-06-BLG-RFC.

CERTIFICATE OF SERVICE

I hereby certify that, on the 26th day of May 2005, I have caused two copies of the Answering Brief of Ranchers Cattlemen Action Legal Fund United Stockgrowers of America and one copy of its Supplemental Excerpts of Record to be served by hand delivery or Federal Express upon:

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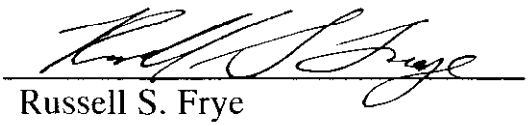

Russell S. Frye

ADDENDUM OF REGULATIONS

Federal Register

Friday,
April 8, 2005

Part VII

Department of Agriculture

Animal and Plant Health Inspection Service

9 CFR Part 93, et al.
Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule; Final Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 98

[Docket No. 03–080–7]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of final rule.

SUMMARY: We are publishing a finding of no significant impact for a final rule concerning bovine spongiform encephalopathy minimal risk regions published January 4, 2005, and, based on that finding, we are affirming the provisions of the final rule. The finding of no significant impact is based on an environmental assessment that documented our review and analysis of potential environmental impacts associated with the final rule and our review of issues raised by the public regarding the environmental assessment. Together, the environmental assessment and our review of the issues raised provide a basis for our conclusion that the provisions of the final rule will not have a significant impact on the quality of the human environment and support our affirmation of the final rule.

DATES: The final rule published January 4, 2005 (70 FR 460), with a partial delay of applicability published March 11, 2005 (70 FR 12112), was effective March 7, 2005. This affirmation of the final rule is effective April 8, 2005.

ADDRESSES: The environmental assessment on which this finding of no significant impact is based may be accessed by any of the following methods:

- On the EDOCKET Web site at *http://docket.epa.gov/edkfed/do/EDKStaff CollectionDetailView?objectId=0b0007d48055a20d.*
- On the APHIS Web site at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.*
- In the APHIS Reading Room in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.
- You may request paper copies of the environmental assessment and the finding of no significant impact by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the titles of these documents when requesting copies.

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

On November 4, 2003, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** and requested comment on a proposed rule (68 FR 62386–62405, Docket No. 03–080–1) to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and to add Canada to this category. The proposed rule also included provisions for the importation of certain live ruminants and ruminant products and byproducts from Canada under certain conditions. Also on November 4, 2003, we made available for public comment an environmental assessment (EA) regarding the potential impact on the quality of the human environment due to the importation of ruminants and ruminant products and byproducts under the conditions of the proposed rule. We carefully considered all comments that addressed the EA, along with those that addressed the proposed rule itself.

On January 4, 2005, we published in the **Federal Register** (70 FR 460–553, Docket No. 03–080–3) a final rule to the proposed rule, to become effective March 7, 2005.[1]

Also in the January 4, 2005, issue of the **Federal Register**, we published a notice (70 FR 554, Docket No. 03–080–4) announcing the availability of, and requesting comments on, a final EA regarding the potential impact on the quality of the human environment due to the importation of ruminants and ruminant products and byproducts from Canada under the conditions specified in the final rule. APHIS' review and analysis of the potential environmental impacts associated with those importations were documented in the final EA, titled "Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products from Canada into the United States, Final Environmental Assessment (December 2004)." We announced that the EA would be available to the public for review and comment until February 3, 2005.

We became aware, however, that the version of the EA that was made available on January 4, 2005, contained some transcription errors that resulted in the omission of several references to an updated APHIS risk analysis regarding the final rule, as well as the incorrect formatting of several source citations. We corrected those errors and, on January 21, 2005, published a notice in the **Federal Register** (70 FR 3183–3184, Docket No. 03–080–5) announcing the availability to the public of the corrected EA and extending the comment period on the EA until February 17, 2005.

We reviewed and considered all issues raised by commenters on the final EA. Of the issues raised by the commenters, some addressed the potential effects of the rule on the environment, while others addressed issues unrelated to such potential effects. Most of these issues had been raised by commenters on the proposed rule and had been previously considered and addressed in our final rule and supporting analyses.

Additionally, shortly after issuance of the final rule, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R–CALF), filed a complaint challenging the rule in the United States District Court for the District of Montana. In that complaint, R–CALF raised several issues regarding the EA that it had not included in either its comments on the proposed rule or in any comment on the final EA. In addition, no other commenter on the EA raised those potential environmental impact issues. Nonetheless, we addressed those issues in our finding of no significant impact (FONSI), discussed below.

We carefully considered environmental issues throughout the rulemaking. Based on the EA and on our review of the comments received on the original and final EAs, on the proposed rule, and in litigation, we have determined that the provisions of our January 4, 2005, final rule will not

[1] On March 11, 2005, the Department published a document in the **Federal Register** (70 FR 12112–12113, Docket No. 03–080–6), effective March 7, 2005, that delayed until further notice the applicability of certain provisions of the final rule. On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of the final rule is preliminarily enjoined.

significantly impact human health or the environment, and that there is no basis in the comments we received and the issues that have been raised to alter the rule. Therefore, we are affirming the final rule as published.

Our FONSI is included in this document under the heading "Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities (Final Rule; APHIS Docket No. 03–080–3), Finding of No Significant Impact." The FONSI includes a discussion of the comments received on the final EA. The EA and FONSI may also be accessed by any of the means listed above under the heading **ADDRESSES**.

The EA and FONSI have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities (Final Rule; APHIS Docket No. 03–080–3)

Finding of No Significant Impact

United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export, Technical Trade Services, 4700 River Road, Unit 38, Riverdale, MD 20737

This finding concludes the environmental assessment process undertaken for the rulemaking, Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities ("MRR rule"). An environmental assessment ("EA"), dated October 2003, was prepared for this rulemaking and it was made available to the public for comment on November 4, 2003. Comments on the EA were received and carefully considered. A final EA was completed and it was made available to the public on January 4, 2005, for a 30-day comment period. On January 21, 2005, a corrected final EA was made available to the public and the comment period was extended for an additional 14 days until February 17, 2005. The corrected final EA had no changes or additions to the version issued on January 4, 2005, other than some specific references to the latest risk analysis for the MRR rule that had been inadvertently omitted from the final EA. This finding summarizes and incorporates by reference the final EA.

Thirteen comments were received in response to our request for comments on the final EA. One was submitted by a state farm bureau federation with certain specific suggestions. This comment counseled caution in implementing the rule for the following reasons. It pointed to the four confirmed cases of bovine spongiform encephalopathy (BSE) in cows of Canadian origin particularly the most recent diagnosis in a cow that was determined to have been born after implementation of a feed ban in Canada—and recommended that USDA confirm that the Canadian feed ban is being effectively enforced before resuming imports of Canadian cattle under 30 months of age and beef from such younger cattle. Additionally, the comment requested that an effective feed ban have been in place in Canada for a full 8 years before cattle over 30 months of age, and meat from such cattle, are allowed to be imported into the United States. It recommended further review of Canada's surveillance program and asked whether the current level of surveillance in Canada is adequate. The comment supported the animal identification provisions in the rule and recommended that appropriate steps be taken to ensure that all imported cattle were slaughtered before 30 months of age. Finally, the comment noted concerns, which we believe are outside the scope of the environmental assessment, about consumer confidence, our ability to regain access to export markets, and potential impacts on producer returns.

One comment, filed by an individual consumer of beef products who asserted he was not associated with any cattle production or processing business, raised five concerns or issues. These included that there was no quantitative risk assessment in the EA, concern about the duration and effectiveness of Canada's feed ban, concern about the tissues defined as specified risk materials (SRMs) under international standards, concern that public health risk was not adequately analyzed in light of recent diagnoses of BSE in Canada and the levels of feed ban compliance and surveillance in that country, and, finally, a recommendation that an environmental impact statement be completed to study the effect of BSE and TSE disease agents in soil, water, air, and the food chain.

Eight comments—one from a South Dakota organization, one from an Oregon organization, and six from individuals, including an assistant state veterinarian—raised a generally similar array of concerns. The thrust of these eight comments is that the commenters believe the risk of introducing BSE into the United States weighs against implementation of the rule. The comments noted support for maintaining the current prohibitions on imports of live animals and beef products from Canada, concerns about the effect of importation into the United States of Canadian cattle and cattle products on U.S. export markets, concern about the effectiveness of the Canadian feed ban and the adequacy of Canada's surveillance program, concerns about feeding animal protein of any kind to cows or sheep, a recommendation for country-of-origin labeling, and support for testing for BSE all cattle of Canadian origin that are in the United States. Again, certain of these issues are outside the scope of the EA. Several of the comments also raised questions about the implications of the most recently confirmed BSE-positive animals in Canada on January 2 and January 11, 2005, including the fact that one of these animals was born shortly after implementation of the Canadian feed ban in 1997.

A comment from a pharmaceutical association noted the importance of animal-derived materials in numerous products. This comment was received on February 24, 2005, 7 days after the close of the extended comment period for the final EA. Nevertheless, because, as the commenter pointed out, it had commented in a timely fashion on the proposed rule and its EA comment was intended to update its recommendations based on recent developments, we will respond to this comment. The comment supported the need to revise what it termed the "binary system" of BSE classification of countries and the adoption of what it termed a science-based approach to identifying minimal-risk regions for BSE as outlined in the rule. The comment, therefore, supported implementation of the rule. It recommended permanently identifying cattle from Canada and distinguishing Canadian and U.S.-origin cattle for the sourcing of bovine raw materials, which would allow companies to make sourcing decisions to satisfy BSE regulatory requirements in the countries to which these companies would ship their products. The association supported the implementation of a national animal identification system.

One comment took issue with the notation in the final EA that alkaline hydrolysis tissue digesters were a preferred method of disposal for BSE-contaminated carcasses. It took issue with that conclusion and suggested the commenter's validated protocol and

process for enzymatic prion degradation was perhaps equally effective. We acknowledge this comment and would welcome more information and data regarding this technology. It is our view, however, that it does not raise an issue that requires discussion in this document. One comment urged the lifting of the prohibitions on camelids because camelids have no demonstrated history of being susceptible to any type of TSE and because these animals are not used for human consumption. We agree with this comment and note that the MRR rule so provided.

Of the issues raised by the commenters, many concerned topics other than the potential effects of the rule on the environment (for example, comments regarding country-of-origin labeling, market access, and consumer confidence). These issues had been raised by commenters on the proposed rule and were considered and addressed by APHIS in its final rule and supporting analyses. Likewise, most of the commenters who did address the potential effects of the rule on the environment raised issues that had already been raised and addressed at considerable length in the final rule and supporting analyses. This fact illustrates the substantial identity of the central animal and public health issues of the rule and the issues evaluated in the environmental assessments.

It is important to note that issues raised in relation to the two most recent BSE-positive cows in Canada on January 2 and January 11, 2005, will be discussed below. Certain commenters observed that these incidents would call into question the effectiveness and adequate duration of the Canadian feed ban. Because these incidents occurred either after or immediately before the publication of the final EA, we welcome the opportunity to respond in this document.

On January 4, 2005, APHIS issued a final rule to amend regulations regarding the importation of animals and animal products to establish a category of regions that present a minimal-risk of introducing BSE into the United States by way of live ruminants and ruminant products and byproducts, and to add Canada to that category. (70 FR 460–553.) The final rule also established conditions for the importation of certain live ruminants and ruminant products and byproducts from minimal-risk regions. Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture may prohibit or restrict the importation or entry of any animal, article, or means of conveyance, or use of any means of conveyance or facility, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. (7 U.S.C. 8303.) The MRR rule will regulate the importation of ruminants and ruminant products and byproducts from Canada in a manner that prevents the introduction of BSE into the United States.

The rule defines a BSE minimal-risk region as one that:

1. Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE in an indigenous ruminant, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

- Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;
- Surveillance for BSE at levels that meet or exceed recommendations of the World Organization for Animal Health (Office International des Epizooties or OIE) for surveillance for BSE; and
- A ruminant-to-ruminant feed ban that is in place and is effectively enforced.

2. In regions where BSE was detected, conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

3. In regions where BSE was detected, took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

These standards are based upon, and are consistent with, international guidelines issued by OIE. For a full analysis and discussion of these standards, see APHIS' November 4, 2003, proposed rule (68 FR 62388–62389) (please note that some revisions were made to the wording of the proposed standards in the final rule) and the update to our risk analysis.[2]

APHIS conducted a comprehensive examination and evaluation of all the relevant risk factors in determining whether Canada qualified as a BSE minimal-risk region. A complete discussion of this evaluation can be found in the risk analysis.[3] In summary, APHIS determined that Canada met the standards for a BSE minimal-risk region because:

1. Canada has implemented comprehensive, effective measures for preventing BSE introduction and the potential for spread within Canada in order to minimize the possibility that infected ruminants, ruminant products, byproducts, or contaminated feedstuffs enter the country. The potential for introduction of the BSE agent into Canada has been limited by import restrictions on meat-and-bone meal (MBM) and live animals. Canada's Animal Disease and Protection Regulations (1978) and Health of Animals Regulations (1991) prohibited importation of MBM from countries other than the United States and, later, from Australia and New Zealand. These rules were first initiated in response to foot-and-mouth disease and later extended to address BSE issues. Canada has not imported live cattle from the United Kingdom (UK) since 1990. In 1994, an import ban was imposed on all countries where BSE had been detected in native cattle, and from 1996 live cattle could only be imported from countries that Canada designated as free from BSE following a comprehensive risk assessment. After detection of BSE in an imported animal in 1993, Canada traced and destroyed and incinerated or repatriated all surviving cattle imported from the UK.

2. Canada has an adult cattle population of approximately 5.5 million cattle older than 24 months of age. The 2004 OIE Code, Appendix 3.8.4, references adult cattle populations as those greater than 30 months and recommends examining at least 300 samples per year from high-risk animals in a country with an adult cattle population of 5 million, or 336 samples per year in a country with an adult cattle population of 7 million. Even though the adult cattle population in Canada is defined as greater than 24 months of age and OIE defines it as greater than 30 months, Canada has met or exceeded this level of surveillance for the past 7 years, thus exceeding the OIE guidelines. Since 1992, the surveillance has been targeted surveillance, with samples obtained from adult animals exhibiting some type of clinical signs or considered high risk for other reasons that could be considered consistent with BSE. From January 2004 through March

[2] See "Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004." pp. 2–5. This update can be viewed on the Internet at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.*

[3] Ibid, pp. 5–18.

2005, over 37,000 samples were obtained. Canadian Food Inspection Agency (CFIA) officials have stated that this surveillance program is designed to detect one case of BSE in one million adult cattle.

3. Since August 4, 1997, Canada has implemented a ruminant-to-ruminant feed ban that is comparable to that existing in the United States and prohibits the feeding of proteins from ruminant species to ruminant animals. Based on CFIA inspections since 2003, virtually 100 percent of Canadian rendering facilities are in compliance with the ruminant-to-ruminant feed ban requirements applicable to this industry. With regard to inspections of feed mills, CFIA reported that, for an annual inspection period of April to March, the fraction of mills reportedly in compliance was 92 percent, 99 percent, and 95 percent for 2002, 2003, and 2004, respectively.[4] CFIA has identified noncompliance of "immediate concern" in fewer than 2 percent of feed mills inspected during 2003–2004. Those instances of noncompliance of "immediate concern" are dealt with rapidly when identified. Noncompliance of "immediate concern" includes situations where direct contamination of ruminant feed with prohibited materials has occurred, as identified through inspections of production documents or visual observation, and where a lack of appropriate written procedures, records, or product labeling by feed manufacturers may expose ruminants to prohibited animal proteins. Accordingly, it is clear that Canada's feed ban is effective.

4. Canada conducted rigorous epidemiological investigations after the BSE cases were detected in May 2003 and December 2003 and after the detections in January 2005.[5] In all but the most recent detection, the cases were animals that were born before the implementation of the feed ban in 1997, with exposure assumed to occur prior to or near the time of the imposition of the feed regulations. The cow in the last detected case was born within a year after implementation of the Canadian feed ban. Although a specific source of infection was not identified, the most likely possibility was the introduction of a low level of infectivity into the animal feed supply originating from an infected animal imported from the UK in the period between 1982 and 1989. These investigations have resulted in the destruction and sampling of a large number of potentially exposed cattle, and results from all testing have yielded no further evidence of infection. CFIA has traced and destroyed the majority of surviving cattle that were birth cohorts of each of the cases of Canadian origin.

5. CFIA imposed new regulations to further strengthen its safeguards against BSE. Measures taken included requiring the removal of bovine SRMs; enhancing enforcement activities associated with the existing cattle identification system; and increasing the level of BSE testing.

Canada has provided comprehensive information throughout this rulemaking regarding its BSE status and the actions it has taken to protect animal and public health and food safety. The most recent Canadian status update can be accessed through the CFIA 2 Web site at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/200503canadae.shtml.*

In summary, the essential factors that led us to conclude that Canada qualified as a BSE minimal-risk region include longstanding Canadian import restrictions, an effective ban on the feeding of ruminant protein to ruminants, the quality of Canada's surveillance and monitoring program, and other measures, such as the required removal of SRMs from cattle at the time of slaughter and enhanced enforcement of Canada's existing mandatory cattle identification system.

APHIS has concluded that the animal and public health measures that Canada has in place to prevent BSE, combined with existing U.S. domestic safeguards and additional safeguards provided in the final rule, provide the utmost protection to U.S. consumers and livestock. With respect to Canadian cattle, the MRR rule will allow the importation of:

- Bovines, for immediate slaughter, or for feeding, as long as they are slaughtered at less than 30 months of age;
- Meat from bovines; and
- Certain other products and byproducts, including bovine livers and tongues, gelatin, and tallow.

The final rule provides the following additional requirements for live Canadian feeder cattle that will ensure they are slaughtered before they reach 30 months of age:

- Feeder cattle must be permanently marked with a brand to identify the BSE minimal-risk region of origin before entering the United States. Feeder cattle exported from Canada will be branded with "C/AN";
- Cattle must be individually identified with an ear tag before entering the United States. This ear tag allows the animal to be traced back to the premises of origin (birth herd);
- Information must be included on the cattle's animal health certification, relating to animal identification, origin, destination, and responsible parties;
- Cattle must be moved to feedlots in sealed containers and cannot go to more than one feedlot; and
- SRMs will be removed from Canadian cattle slaughtered in the United States in accordance with FSIS regulations.

Based on our risk analyses, APHIS concluded that the cumulative effect of all of the measures in place in Canada and the United States, and the additional measures imposed by the final rule, is an extremely effective set of interlocking, overlapping and sequential barriers to the introduction and establishment of BSE in the United States.[6] The preceding discussion and conclusions provide the foundation for the finding of no significant impact described below.

The final rule was scheduled to become effective on March 7, 2005. On February 9, 2005, the Secretary of Agriculture announced that the provisions of the final rule allowing the importation of beef products from cattle over 30 months of age would be delayed.[7] On March 2, 2005, the United States District Court for the District of Montana issued a preliminary injunction that enjoined implementation of the MRR rule.

Pursuant to the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), the purpose of an environmental assessment is to provide sufficient information and analysis to agency decision makers to allow them to determine whether the proposed agency action will have a significant effect on the human environment. If a determination is made that the action would have a significant effect on the human environment, the agency is obligated to prepare an environmental impact statement. If a determination is made that the action will not have a significant effect on the human environment, a finding of no significant impact is issued.

The two EAs issued for the MRR rule considered two alternatives: (1) The "No

[4] Canadian Food Inspection Agency (CFIA). Memorandum from Dr. Brian Evans, Chief Veterinary Officer, to Dr. John Clifford, Deputy Administrator, VS, APHIS. July 30, 2004.

[5] Canadian reports of the investigations can be accessed at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bseesbindexe.shtml.*

[6] See "Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004." pp. 25–27.

[7] On March 11, 2005, APHIS published a notice in the **Federal Register** delaying the applicability of the provisions of the rule relating to beef products and byproducts from bovines 30 months of age or older (70 FR 12112).

Action" alternative, which would maintain the continued regulatory prohibition of the importation of ruminants, ruminant products, ruminant by-products from Canada and from any other country or region that could eventually be classified as a BSE minimal-risk region pursuant to the rulemaking and (2) the preferred alternative, which will allow for the importation of certain ruminant products and by-products and certain ruminants, providing the country or region seeking recognition as a BSE minimal-risk region demonstrates that it meets the relevant factors consistent with standards recommended by the OIE.

The environmental issues involved in this rulemaking, including those raised in comments on the two EAs as well as in litigation, are discussed below.

A. The Degree to Which the Action May Affect Public Health or Safety

The introduction of BSE into the United States has the potential to affect both human and animal health. BSE, commonly known as "mad cow disease," is a disease that belongs to a family of mostly very rare diseases known as TSEs. Cases of BSE in cattle were first reported in the UK in 1986. To date, over 95 percent of all known BSE cases worldwide have occurred in the UK. Within cattle herds, BSE is not contagious and does not spread from animal to animal. It is spread to cattle primarily through the consumption of animal feed containing protein from ruminants infected with BSE. In 1996, a new disease, variant Creutzfeldt-Jakob disease or vCJD, was detected in humans and linked to the BSE epidemic in cattle. Consumption of cattle products contaminated with the BSE agent is reported to be the cause of vCJD. Approximately 153 cases of vCJD have been identified worldwide and 95 percent of these cases have been linked to exposure in the UK. When compared with the significant number of cattle exposed to BSE, the relatively small number of cases of vCJD indicates a substantial species barrier that protects humans from widespread illness due to BSE exposure.

As previously discussed, the MRR rule amends APHIS' regulations to allow the importation of certain ruminants, ruminant products and by-products from regions that pose a minimal risk for BSE. The rule will preclude introduction of BSE into the United States and will ensure the protection of domestic livestock and the food supply. The MRR rule is fully consistent with the guidelines and recommendations of the OIE for trade in animals and animal products from BSE-affected countries.

In determining whether it was necessary to continue the prohibitions and restrictions on imports from Canada pursuant to the Animal Health Protection Act, APHIS analyzed the risks associated with such imports. The analysis is consistent with OIE guidelines and the internationally recommended components for animal health import risk analysis. The risk analysis drew on a number of sources of information, including: Previous analyses of risk conducted by APHIS; scientific literature; results of epidemiological investigations; data provided by the Canadian Government; a quantitative analysis of the risk of BSE in Canada; quantitative analyses of the consequences of BSE being introduced into the United States; measures implemented by USDA's Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) to protect against human exposure to the BSE agent in the United States; reports by international review teams; and the BSE guidelines adopted by the OIE. The determination to allow imports of certain Canadian ruminants and ruminant products was based on a thorough evaluation of the BSE risk in Canada, the potential for BSE infectivity to be introduced into the United States, the potential spread of BSE in cattle and possible human exposure if BSE infectivity were introduced into the United States, and the likelihood that BSE could become established in the United States.

A great deal is now known about BSE. There is a strong scientific consensus about the BSE agent, the mechanisms for its spread, and the tissues that are most likely to harbor the infective agent. Scientific research, backed by practical experience, has resulted in a defined series of measures that countries can use to keep the BSE agent out of the food and feed chain and thus ensure the safety of animal and public health. APHIS has concluded that such measures are in place in Canada and the United States. The risk analysis contains a comprehensive discussion of the facts and circumstances relevant to Canada's BSE status and of the mitigation measures in place in both Canada and the United States that will ensure that BSE is not introduced into the United States. The critical country-of-origin factors leading to APHIS' conclusion and this finding of no significant impact are:

1. *Import Restrictions*—Canada has implemented effective methods for preventing the introduction of BSE into its herd by restricting the importation of live ruminants and meat-and-bone meal from any country that had not been recognized as BSE-free following a comprehensive risk assessment.

2. *Surveillance*—Canada has been actively monitoring for BSE in its herd since 1992 and has met or exceeded the OIE recommended level of BSE surveillance for the past 7 years. The number of cattle tested annually has steadily increased over the years, and in 2003, approximately 5,700 cattle were tested. In 2004, more than 23,500 animals were tested. In 2005, more than 14,000 samples were tested as of March 23.

3. *Feed Ban*—Canada and the United States implemented substantially identical feed bans simultaneously in 1997 that prohibit the feeding of mammalian protein to ruminants. Canada's feed ban is more stringent than the feed ban in the United States, as it prohibits the use of plate waste and poultry litter in ruminant feed. The Canadian feed ban has been effective and has a strong compliance and enforcement component. It is also important to note that Canada established its feed ban 6 years before identifying its first case of BSE in May 2003.

4. *Epidemiological Investigations*—Canada has the capacity to conduct, and has conducted, rigorous investigations of its BSE findings. These investigations have included trace-outs of cattle that may have been exposed to the same feed sources as infected cattle and of rendered protein products that could have included the tissues from the infected animals. These investigations have been successful due in part to the mandatory cattle identification program in Canada.

5. *Removal of SRMs*—Both Canada and the United States require the removal at slaughter of SRMs—those tissues most likely to harbor the BSE infective agent—and prohibit the use of SRMs in human food.

In addition, there are several biological factors that support the finding herein with specific reference to the importation of live animals and animal products. These factors include: The age of the animal, tissue distribution and infectivity, and feed source and exposure. Our findings with respect to these factors are detailed in the final risk analysis associated with this final rule.[8] Furthermore, as explained in the exposure assessment

[8] See "Analysis of Risk—Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004," pp. 11–17.

component of the risk analysis, our evaluation of slaughter controls in place in both the United States and Canada, rendering inactivation factors, feed manufacturing controls both in the United States and Canada, and of the likelihood that an animal would ingest an infectious dose and would develop the disease provides further support for our finding of no significant impact.

Finally, the additional post-entry mitigation measures imposed by the final rule enhance protection of animal and human health and further ensure that there will be no significant impacts. The MRR rule requires that live cattle under 30 months of age can only enter the United States for immediate slaughter or for feeding and slaughter. Movement of these cattle is carefully controlled by requiring each animal to have permanent identification that identifies its country of origin, and a special permit designed to account for the inventory of cattle consigned to their point of destination. The rule, therefore, ensures that those cattle are identified and remain accounted for through slaughter.

Based on all these factors, APHIS concluded that there was no scientific basis to believe that the importation from Canada of live ruminants (including cattle less than 30 months of age) and ruminant products (including beef products and byproducts) in accordance with the conditions required in the rule pose any risk of introducing BSE into the United States. For all the reasons discussed in section VI.A. of the final EA, the safeguards in place in both the United States and Canada, coupled with the additional risk mitigation measures required in the MRR rule fully protect both animal and public health.

B. The Degree to Which the Effects on the Quality of the Human Environment Are Likely To Be Highly Controversial or the Degree to Which the Possible Effects on the Human Environment Are Highly Uncertain or Involve Unique or Unknown Risks

Controversy exists when substantial questions are raised as to whether an action may cause significant degradation of an environmental factor. In the context of an EA under NEPA, controversy refers not to the existence of public opposition, but to a substantial dispute about the size, nature, or effect of the action. Even if an action is projected to have a controversial effect, the agency nonetheless has the discretion to be guided by the expertise and judgment, as well as the practical experience, of its own experts. There is a presumption in favor of the agency's expert advice and guidance.

In the case of the MRR rule, there is no significant controversy with regard to the science underlying the mitigation measures that form the basis of the rule, and the effectiveness of the mitigation measures that are in place in Canada and the United States or prescribed as additional requirements in this rule. While questions remain about BSE and research continues on BSE as it does for many animal diseases, there is substantial knowledge about the disease and effective mitigation measures, and a solid scientific consensus among animal health experts both in the United States and internationally. Based upon this substantial body of scientific research, field epidemiological investigations and years of practical experience and observations by animal health authorities, very effective measures have been identified to prevent the introduction and spread of BSE and these measures have been put in place in the United States and Canada and are embodied in the MRR rule.

Two principal concerns are expressed in comments filed on the EA in opposition to the MRR rule. First is the perceived risk that BSE would be introduced into domestic cattle and, second, that vCJD could occur as a result of such introduction or through the import of meat products from Canada. APHIS has concluded that the MRR rule will preclude the introduction of BSE and that the comprehensive animal and public health measures in place in Canada and in the United States will prevent these effects from occurring. In this regard, we must note that while APHIS' principal responsibilities encompass animal and plant health, FSIS and the FDA are the agencies principally responsible for public health and food safety. Both of these agencies have implemented regulations to ensure that the BSE agent does not enter either the human or the ruminant food chain.[9] In developing the MRR rule and in preparing the EA, APHIS consulted with both FSIS and FDA.

This rule is based upon and is fully consistent with an international scientific consensus that is embodied in the guidelines and recommendations of the OIE. OIE is the internationally recognized authority on animal health issues and currently has 167 member countries, including the United States and Canada. OIE develops and publishes standards, guidelines and recommendations for international trade in animals and animal products. These standards and guidelines are recognized by the World Trade Organization as the reference international animal health rules for animal diseases and zoonoses and they are codified in the Terrestrial Animal Health Code and the Aquatic Animal Health Code. The standards, guidelines and recommendations are developed by specialist commissions and experts based on the latest and best available scientific research and data and are adopted by consensus of the OIE member countries. The aim of the Terrestrial Animal Health Code is to facilitate the safe international trade of animals and animal products. This is achieved through recommendations on risk management measures for specific diseases to be used by national veterinary authorities or other competent authorities of importing and exporting countries when establishing health regulations for the safe importation of animals and animal products. The aim of the OIE's work in this regard is to avoid the transfer of agents pathogenic for animals and humans, without the imposition of unjustified trade restrictions. With respect to the OIE guidelines for BSE, it is important to note that the OIE does not recommend that an importing country completely ban the importation of live cattle and meat products even when the importing country determines that the exporting country has a high BSE risk status. For the details of the BSE chapter of the Terrestrial Animal Health Code, see *http://www.oie.int/eng/publicat/en_code.htm.*

Many of the 13 commenters on the final EA opposed implementation of the MRR rule out of a concern that BSE would be introduced into the United States, a concern raised in part by the 2 confirmed cases of BSE in Canada in January 2005. These commenters did not elaborate on the basis for their concern or whether they disagreed with the scientific foundation of the MRR rule. On the other hand, some commenters who expressed concerns about the implementation of the MRR rule acknowledged, implicitly or explicitly, the validity of the scientific

[9] See: FSIS' interim final rule published in the **Federal Register** on January 12, 2004, titled "Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (69 FR 1874–1885, FSIS Docket No. 03–025IF.); FDA interim final rule published in the **Federal Register** on July 14, 2004, titled "Use of Materials Derived from Cattle in Human Food and Cosmetics" (69 FR 42255, FDA Docket No. 2004N–0081); FDA's ruminant feed regulations in 21 CFR 589.2000; and an advance notice of proposed rulemaking issued jointly by FDA, FSIS, and APHIS in the **Federal Register** on July 14, 2004, titled "Federal Measures to Mitigate BSE Risks: Considerations for Further Action" (69 FR 42288–42300, FDA Docket No. 2004N–0264, FSIS Docket No. 04–021ANPR, APHIS Docket No. 04–047–1).

approach embodied in the rule but urged the agency to ensure that the measures the agency relies upon have been effectively implemented. For example, the state farm bureau federation urged that USDA "investigate and confirm" that the current feed ban is being effectively enforced prior to opening the border with Canada. Additionally, the federation urged that USDA assess whether Canada's surveillance program is adequate.

Four cases of BSE have been detected in Canadian-origin cattle. The first two positive cases were detected in 2003 and two cases have been detected in 2005. On January 2, 2005, Canada announced that it had confirmed a case of BSE in an 8-year-old dairy cow in Alberta, Canada.

The following week, on January 11, 2005, Canada announced that it had confirmed a case of BSE in a beef cow in Alberta that was born shortly after the implementation of the feed ban in 1997. Because the cow was born shortly after the implementation of the feed ban and, in addition, to determine if there were any previously unidentified potential links, the USDA sent two technical teams to Canada to evaluate the circumstances surrounding these two recent BSE findings. One team, consisting of USDA and FDA officials, was responsible for conducting an in-depth assessment of Canada's feed ban, and the other team focused on the epidemiological investigations of the positive cases.

In preparing the MRR rule, Canada's compliance with the feed ban was thoroughly considered and discussed. Canada implemented its feed ban in 1997 to prohibit the feeding of most mammalian protein to ruminants. Canada's feed ban is virtually identical to the feed ban in place in the United States, except that Canada has extended its ban by prohibiting plate waste and poultry litter from being fed to ruminants. APHIS concluded, based on this thorough assessment, that Canada has had an effective feed ban in place in the rendering, feed manufacturing and livestock industries. (70 FR 467–468, APHIS Docket No. 03–080–3; "Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004," pp. 7–10; see also BSE in Canada Status Update—March, 2005, which can be found at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/200503canadae.shtml.*)

On February 25, 2005, USDA published its assessment of the Canadian feed ban. The team concluded, based on its review of inspection records for the last 3 years and on-site inspections of commercial feed mills and rendering facilities, that Canada has a robust inspection program with strong enforcement, that overall compliance with the feed ban is good, and that the feed ban is effectively reducing the risk of transmission of BSE. (*http://www.aphis.usda.gov/lpa/issues/bse/bse.html.*) The team's report confirmed the APHIS evaluation of Canada's feed ban which supported the MRR rule.

It is important to note that in 1997, BSE had not been detected in North America, and the feed bans implemented by Canada and the United States were precautionary measures. As a result, neither government required that existing feed stocks be recalled. In Canada specifically, the feed ban was implemented with provisions for a phase-in period so that existing stocks of feed material could be depleted. It is likely that the Canadian feed ban took some time to be implemented completely throughout the feed manufacturing industry, as did the United States' feed ban. This would be expected in implementing a new, comprehensive regulatory program.

With respect to the two most recent positive BSE cases, the Canadian government confirmed that the animal identified as positive on January 2nd was exposed to feed rations containing meat and bone meal that was produced prior to the 1997 feed ban. This animal was born in October 1996 and was exposed to rations that contained meat and bone meal in early 1997, before the feed ban was implemented. In the case confirmed on January 11th, the Canadian investigation concluded that BSE may have been transmitted to the affected animal through feed produced shortly after the feed ban was implemented. As described in the previous paragraph, since an extensive change in industry practices cannot be expected to be completed immediately, a finding of BSE in an animal born shortly after the feed ban would not be unexpected and would not be inconsistent with the risk analysis supporting the final rule. (See BSE in Canada Status Update—March, 2005, which can be found at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/200503canadae.shtml.* See also the summary report of the CFIA investigation of the January 2, 2005, case of BSE at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/2investe.shtml* and the summary report of the CFIA investigation of the January 11, 2005, case of BSE at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/3investe.shtml.*)

The possibility of additional BSE positive animals was understood and carefully considered by APHIS in the risk analysis and in our determination that Canada qualifies as a minimal-risk region. In our final rule (70 FR 514), we acknowledged the possibility that additional BSE-infected cattle might exist in Canada and explained the reason for our confidence that the number of such additional infected animals, if any, would be small. First, Canada has not imported ruminant MBM from any country with BSE since 1978. Second, Canada has prohibited the feeding of ruminant MBM to ruminants since 1997, and CFIA has verified high levels of compliance with the feed ban by routine inspections of both renderers and feed mills. Third, Canada has traced and destroyed all remaining cattle imported from the UK. Fourth, Canada has traced and destroyed the majority of the cattle that comprised the birth cohorts of the two initial Canadian BSE cases, as it has subsequently done with the birth cohorts of the two most recent cases. Fifth, Canada has conducted surveillance for BSE since 1992 and has conducted targeted surveillance at levels that have met or exceeded OIE guidelines since 1995.

As we explained in our final rule, even if BSE-infected cattle do remain in Canada, they are likely to be older animals that were exposed before Canada's feed ban in 1997. Because this rule requires that imported animals be less than 30 months old, such animals could not legally enter the United States under this rule. Further, even if an infected animal did enter the United States, the science, the research, and the experience of animal and public health authorities, supported by the Harvard-Tuskegee Study indicates it would be very unlikely to lead to the introduction of BSE into domestic cattle or to human exposure to the BSE agent.

Several commenters on the EA questioned Canada's feed ban due to press reports published in December 2004 that revealed that animal protein of undetermined origin had been found by CFIA in ruminant feed. As part of its ongoing compliance and enforcement program, the CFIA conducted a small feed sampling and testing program to evaluate the usefulness of direct microscopy. CFIA concluded that microscopy was not capable of distinguishing between animal tissues that pose no animal health risk and those that are prohibited under Canada's

feed ban regulations. In following up on the microscopy results, the CFIA concluded the great majority of samples did not contain prohibited material. Of the 110 samples tested, 65 samples were of Canadian origin, 44 samples were from the United States, and one was from France. Of the 65 samples of Canadian origin, the CFIA was unable to rule out the possibility that some incidental level of prohibited material may have been present in 11 samples. Of the 45 imported samples, animal material was detected in 18. With respect to the Canadian origin samples, the CFIA has taken action to ensure that the establishments involved have improved their recordkeeping, flushing, and/or sequencing procedures. (*http://www.inspection.gc.ca/english/anima/feebet/rumin/microe.shtml.*) Based on our extensive experience and interaction with CFIA program officials over many years, the thorough Canadian report on the microscopy sampling and testing program, as well as the results of the APHIS feed team inquiry, APHIS has concluded that the Canadian feed ban is effective and will accomplish its objective of reducing and eliminating any BSE infectivity that may remain in Canada.

As noted above, several commenters expressed concern that the MRR rule could result in the introduction of BSE into the domestic herd and that vCJD could occur as a result of such introduction or through the import of meat products from Canada. With regard to this concern, there is a solid scientific consensus regarding our knowledge of the cattle tissues that contain BSE infectivity and our knowledge of the modes of transmission of that infectivity. While it is likely that ongoing research will increase our knowledge of the disease agent, APHIS, along with FSIS and FDA, are confident that the measures in place will protect animal and human health. In addition, it seems clear that there is a significant species barrier that protects humans from illness due to exposure to the BSE agent. European scientists working on the outbreak in the UK and subsequent BSE research have suggested that the amount of infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle. During the epidemic in the UK, it was estimated that there were approximately 1 million infected animals and yet, to date, there have been only approximately 153 vCJD cases worldwide, 95 percent of which have occurred in the UK. Current research does not suggest the need for further food safety mitigations and does not alter the conclusion that the appropriate tissues that can carry levels of infectivity sufficient to cause human or animal illness are, in fact, being removed from the animal and human food supply under U.S. and Canadian regulations.

One commenter suggested the need for further assessment of the persistence of the BSE agent in soil, water and air. To date, there is no evidence of environmental transmission of the BSE agent. While such transmission could be theoretically possible, epidemiological reviews do not indicate that such transmissions, even if they occurred, would be a significant issue. In the UK, which has experienced the largest and most significant outbreak, early epidemiological investigations pinpointed feed as the route of transmission. In response to these findings, the UK authorities instituted feed ban regulations that have been strengthened over the years. The feed restrictions have clearly had an effect in preventing transmission of disease, with the number of cases identified annually continuing to decrease from a peak in 1992–1993. Investigations have been done on animals born after the reinforced ban went into effect. These have included evaluating all possible routes of transmission, and they continue to conclude that environmental contamination is an unlikely risk factor. Therefore, based on the best available science, the ability of the BSE agent to persist in soil, water and air is not a significant issue.

While there is evidence that scrapie disease in sheep and chronic wasting disease (CWD) in cervids can be transmitted by environmental contamination, there is no basis for extrapolating these data to BSE in cattle. Research has demonstrated that the distribution of scrapie infectivity in sheep is different than the BSE agent in cattle. For example, infectivity has been found in the placenta of sheep infected with scrapie. This contributes to the lateral transmission (animal-to-animal) of scrapie in sheep, and if placental tissue remains in the environment, it can contribute to environmental contamination. Conversely, in cattle infected with BSE, no infectivity has been demonstrated in placenta and there is no evidence of lateral transmission of the disease. Similarly, animal-to-animal contact appears to contribute to the spread of CWD in cervids, and environmental contamination also appears to be a factor, although the specific means of transmission is unknown. However, these findings cannot be extrapolated to cattle with BSE, as there is no evidence of lateral transmission of BSE or of transmission by environmental contamination.

C. The Degree to Which the Action May Establish a Precedent for Future Action With Significant Effects or Represent a Decision in Principle About a Future Consideration

This criterion requires consideration of whether an action may establish an authoritative rule, pattern, or practice for similar cases that may follow and whether the precedent thereby established could have significant effects on the quality of the human environment.

The MRR rule establishes standards for recognizing regions as presenting a minimal risk of introducing BSE into the United States and provides for the importation of certain ruminants, ruminant products and byproducts from such regions. The minimal-risk region standards and import conditions established by APHIS are designed to prevent the introduction of BSE into the United States. These standards and conditions are buttressed by a series of interlocking, overlapping risk mitigations in place in the United States. The addition of this minimal-risk category to the agency's BSE rules will permit regions that believe they meet the standards to request recognition as a BSE minimal-risk region. We would expect and require that any such request will, in the first instance, comply with § 92.2 of the APHIS regulations, which contains the general procedures for requesting the recognition of regions. (9 CFR 92.2.) The MRR rule, however, designates Canada as the only minimal-risk region for BSE. Before another country or region would be recognized as a BSE minimal-risk region, APHIS would conduct an assessment of all risks involved. If the risk assessment indicated that the region meets the standards and appropriate requirements, APHIS would publish a proposal in the **Federal Register**. At that point, the public would have an opportunity to participate fully and all pertinent issues, questions, and concerns would be addressed in the rulemaking process. Needless to say, any unusual or unique facts or circumstances related to a particular region's request would be carefully evaluated by APHIS as well. For example, the animals or animal products allowed to be imported and the required risk mitigation measures could and would be tailored to each specific region considered. Accordingly, the MRR rule does not establish a precedent for future actions with significant effects or represent a decision in principle about future

approval of additional minimal-risk regions.

D. Whether the Action Is Related to Other Actions With Individually Insignificant but Cumulatively Significant Impacts

The term cumulative impact is defined as an impact on the environment that results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.

The potential for harm to the quality of the human environment lies in the introduction of the BSE agent into the United States and subsequently finding its way into the animal and human food supply where it could be ingested and result in infection. For this chain of events to occur, the multiple animal and human health mitigation measures in place in Canada and the United States, as well as the additional mitigations prescribed by the MRR rule, would have to substantially fail. There is no basis to conclude that such a significant breakdown in the system of interlocking and overlapping measures could ever occur. Similarly, if the agency were to recognize any other regions as minimal-risk regions, there is no reason to believe that the mitigation measures and other requirements imposed in such a rulemaking would be any more likely to be breached and result in harm to animal or human health. It must be remembered that our MRR rule is designed to preclude the introduction of BSE into the United States and APHIS has concluded that the rule will achieve that result. Accordingly, there is no basis to believe that this action, or future actions that the agency may take, could result in cumulatively significant environmental impacts.

Additional Issues: Allegations of Environmental Impacts Raised in Litigation

Shortly after issuance of the final EA for the MRR rule, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America ("R–CALF"), filed a complaint challenging the rule in the United States District Court for the District of Montana. R–CALF alleged that the final EA was inadequate because, among other things, it failed to assess the environmental effects of transporting what we estimated would be as many as 2 million head of cattle from farms and feedlots in Canada to feedlots and slaughterhouses in the United States, as well as the environmental impacts of feeding and holding these additional feeder cattle until slaughter. Although the plaintiff filed several comments on the rule throughout this rulemaking proceeding, it did not include these concerns in these comments, nor did it file any comment on the final EA published on January 4, 2005. In addition, no other commenter on the EAs raised these potential environmental impact issues. Even though the alleged potential effects pose no significant environmental impact, and were not raised by R–CALF or any other commenter on the EA, we have addressed them below.

The two issues raised by R-CALF did not, and do not now, pose potentially significant impacts. Accordingly, they were not discussed in the final EA. First, it is important to note that the impacts or effects alleged by R-CALF to be significant are not brought about or caused by the MRR final rule. Second, it is also important to understand the MRR rule within the context of the economic relationship that has existed between Canada and the United States for many years. Since the 1970's, the U.S. and Canadian cattle and beef industries operated largely as an integrated North American industry, with both live cattle and processed beef flowing freely between the two countries. For years prior to May 2003, millions of head of live cattle crossed the border in one direction or the other. The two countries have become each other's largest trading partners in agricultural products.

In May 2003, as a result of the finding of BSE in Canada, APHIS published an interim rule to add Canada to the list of countries in which BSE exists. APHIS took this action as a temporary measure while it assessed the facts and circumstances surrounding the BSE situation in Canada. After evaluating the epidemiological investigation of the May 2003 BSE positive cow and after reviewing the BSE risk mitigation measures in place in Canada and the United States, USDA announced in August 2003 that it would begin issuing permits, pursuant to its existing regulations, to allow the importation of certain low-risk meat products from Canada. These products included boneless beef from cattle under 30 months of age, veal, and bovine liver. As a result, within 3 months, a substantial amount of trade in beef and beef products was resumed with Canada. In November 2003, APHIS issued a proposed rule that would again allow the importation of certain live animals, including cattle under 30 months of age, as well as all beef products from cattle under 30 months of age, from Canada. Therefore, the MRR rule would allow the restoration of trade in ruminants and ruminant products under approved mitigations after a temporary suspension of such trade.

The final economic analysis for the MRR rule estimated that as many as 2 million head of cattle could be imported from Canada in 2005, assuming implementation of the MRR rule at the beginning of the year. This estimate was based on historical cattle import data from 2001 and 2002, an estimated backlog of cattle in Canada as a result of the temporary closure of the border to live cattle in 2003, and an estimate of the number of cattle under 30 months of age that would be available for importation into the United States because of an increase in the number of older cattle that would be slaughtered in Canada for the export of beef to the United States. We acknowledged that there was a good deal of uncertainty in projecting the number of cattle that would be imported from Canada and that changes in production, feeding, slaughter and trade patterns and circumstances could well affect the result. In recognition of these uncertainties, we also conducted the analysis using one-half of the assumed backlog and one-half of the assumed number of imported fed cattle displaced from slaughter in Canada.

Using the 2 million number, R–CALF estimated that the resumption of limited trade in live cattle would result in 35,000 truck round-trips between Canada and the United States. Assuming these would represent an actual increase in trips involving live cattle and meat, the truck traffic represented by this estimation is wholly insignificant. For 2003, the incoming truck crossings from Canada into the United States totaled 13.3 million crossings, which included 6.7 million truck crossings, 5.7 million loaded truck container crossings, and 0.9 million unloaded truck container crossings. (*See http://www.bts.gov/programs/international/border_crossing_entry_data/.*) For 2002, the total incoming truck crossings from Canada into the United States were 13.7 million crossings, which included 6.9 million truck crossings, 5.8 million loaded truck container crossings and 1.0 million unloaded truck container crossings. (*Id.*) For 2001, the total incoming truck crossings from Canada into the United States were 13.4 million crossings, which included 6.8 million truck crossings, 5.6 million loaded truck container crossings, and 1.0 million unloaded truck container crossings. (*Id.*)

There is little variation in the annual volume of truck traffic entering the United States from Canada over this 3-year period, and, in addition, an increase of 35,000 truck crossings would be well within the variation shown by the data. Even with an increase of 35,000 truck round-trips between Canada and the United States, the total increase would amount to approximately 1/4 of one percent increase in truck traffic, an amount that is *de minimus* by any measure. An examination of truck traffic through the 20 ports of entry through which importations of live ruminants and ruminant products from Canada are authorized under the MRR rule yields similar conclusions. The 2003 truck crossings at the 20 ports of entry were approximately 11.1 million. (*Id.*) Therefore, an increase of 35,000 truck crossings spread over just these 20 ports of entry would result in less than 1/3 of a one percent increase. It is also important to note that truck traffic between the United States and Canada is merely a subset of all vehicular traffic between the two countries. When considering the total volume of all vehicular traffic traveling across the border with Canada, the environmental impacts associated with an increase of 35,000 truck round-trips are even less significant. Accordingly, R–CALF's claim that increased truck traffic would result in environmental damage is without merit.

R–CALF also alleges that there will be significant environmental effects attendant to the importation of live animals for feeding and for slaughter. R–CALF asserts that these live cattle would be required to be moved to a limited number of feedlots and slaughter facilities in the United States. However, the final regulation contains no limitation on the number of feedlots or slaughter facilities. The MRR rule is merely restoring, for live cattle under 30 months, longstanding trade with Canada, trade that has persisted for years and was only temporarily halted in May 2003 due to the finding of BSE in Canada. There is no reason to believe that these cattle would be destined for a different set of feedlots or slaughter facilities than cattle imported from Canada prior to 2003.

Whatever the potential environmental effects that theoretically might be associated with the importation of live cattle for feeding or for slaughter, there would be a significant difference in the magnitude of such potential effects depending on whether the cattle were being transported directly to slaughter facilities or were destined for feedlots, where they may be fed for some period of time prior to moving to slaughter. The potential environmental effects, while inconsequential, would be significantly less for cattle moved immediately to slaughter facilities. Based on historical data for cattle imports from Canada, between 65 percent and 75 percent of imported cattle have gone directly to slaughter and the remainder (other than the very small number historically imported for breeding) have been transported to feedlots and then to slaughter facilities. Based on the projection in the final economic analysis of 2 million cattle imported, approximately 1.4 million would be moved immediately to slaughter and 600,000 feeder cattle would be moved to feedlots.

Subsequent to the estimates in the final economic analysis and publication of the MRR rule, on February 9, 2005, the Secretary announced that implementation of the part of the MRR rule that would allow for importation of beef from cattle 30 months of age or older would be delayed. Therefore, there was no longer a basis for assuming the displacement from slaughter in Canada of cattle under 30 months of age by cattle 30 months of age or older. The estimate of the number of cattle that would be imported from Canada was revised downward. We further modified the estimate downward to reflect an increase in Canadian slaughter capacity over the past year. Therefore, based on these factors, we estimated that as many as 1.4 million cattle could be imported from Canada in the first year after the effective date of the MRR rule. Of this number, we estimate that 900,000 fed cattle would be moved directly to slaughter facilities and that 500,000 feeder cattle would be sent to feedlots and then to slaughter, further reducing any potential impacts.

On January 6, 2005, the National Cattlemen's Beef Association (NCBA) sent a delegation of U.S. cattle producers to Canada on a fact-finding mission regarding BSE and the MRR rule. One task assigned to the NCBA delegation was to identify Canadian cattle that would qualify for export under the MRR rule and determine the impact on U.S. producers. The NCBA delegation report, dated February 2, 2005 (*http://www.beefusa.org/uDocs/acf985911.pdf*) stated, based on Can-Fax data gathered over a 20-month period of time, that there were approximately 900,000 head of cattle available for export. This consisted of approximately 600,000–700,000 head of fed cattle and approximately 200,000–300,000 feeder cattle. The NCBA report suggested that the import quantities assumed in APHIS' economic analysis were too high. The NCBA report suggests that the APHIS estimate did not fully account for the 22 percent increase in Canadian slaughter capacity between 2003 and 2004. The NCBA report concluded that the delegation agreed with Can-Fax and other private sector estimates and put the likely imports of feeder cattle in the range of 200,000–300,000 during calendar year 2005 and assumed that the MRR rule would be implemented on March 7, 2005.

Under either of APHIS' two estimates, any environmental effects would not be significant. The average annual number of fed cattle slaughtered for the years 2002 and 2003 in the United States was 29 million. Total cattle slaughter, which includes fed cattle, cows and bulls, averaged 35.6 million head annually for the same period. Thus, the estimated maximum imports of cattle for immediate slaughter would amount to approximately 4.8 percent of the total fed cattle slaughter and 3.9 percent of total cattle slaughter spread over a 12-month period. For the years 2003 and 2004, an average of 26.9 million cattle were marketed by U.S. feedlots annually. The estimated number of feeder cattle that may be imported from Canada in the first year (500,000–600,000 head) would represent between 1.8 and 2.2 percent of fed cattle marketed annually in the United States. Even assuming that Canadian feeder cattle actually imported after implementation of the MRR rule represented an actual increase in the number of cattle on feed in the United States, the potential effects would not be significant. The transitory nature of even this volume of imports from Canada is discussed in the final EA, where estimates that imports would decline over the years 2006–2009 are discussed and displayed.

Furthermore, any potential impacts on air and water quality associated with the importation of cattle from Canada are addressed under an array of existing statutes and regulations in the United States. These regulations include the National Pollutant Discharge Elimination System Permit regulations and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFO) under the Clean Water Act, as well as State environmental regulations for proper management of manure and wastewater from animal feedlot operations. In addition to state laws and regulations for air emissions, there are a variety of provisions under the Clear Air Act that could address air emissions relating to this activity. The U.S. Environmental Protection Agency has also established requirements for CAFOs under the

Clean Water Act and regarding nitrate contamination of underground sources of drinking water under the Safe Drinking Water Act. The United States' Clean Air Act and Canadian environmental protection laws have vehicle emissions requirements that are designed to prevent harmful air emissions from vehicles, including transport trucks. These activities have a very low potential to negatively affect human health and safety since each is subject to comprehensive environmental regulation in this country and in Canada. Compliance with these requirements by transporters, feedlot operators, and slaughterhouses assures that the quality of the human environment will be safeguarded in all respects. Our border ports are adequately staffed and capable of handling movement of cattle into this country, which will not concentrate at a single border port. Historically, Canadian cattle imported into the United States for slaughter have been shipped to numerous States throughout the United States. Because cattle are not required to be shipped to specific feedlots or slaughter facilities, it is expected that trucks will utilize all available border crossings and highway routes. There is no evidence or data to suggest that our roadways, feedlots, and slaughterhouses, as currently operated, cannot accommodate the resumption of Canadian cattle imports in a manner that fully protects all potentially impacted environmental quality values.

I have determined that the final BSE MRR rule will not have a significant effect on the human environment and accordingly I have decided that it is appropriate to issue a finding of no significant impact for the final MRR rule. Thus, having fully considered the two environmental assessments prepared for the MRR rule, as well as all of the comments submitted on them, along with the reports and analyses referenced in the EA and in the MRR rule, I conclude that the MRR rule will protect animal and human health and the environment. Accordingly, I find that adoption of the MRR final rule and the recognition of Canada as a BSE minimal-risk region will not significantly affect the quality of the human environment.

The finding of no significant impact was signed by Dr. W. Ron DeHaven, Administrator, Animal and Plant Health Inspection Service, on April 5, 2005.

Done in Washington, DC, this 5th day of April 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 05–7141 Filed 4–7–05; 8:45 am]

BILLING CODE 3410–34–P

Regulatory Flexibility Act

As Acting Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this rulemaking will not have a significant economic impact on a substantial number of small entities because it primarily affects Federal employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this amendatory rulemaking does not contain information collection requirements that require the approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), the final rule will not significantly or uniquely affect small governments and will not result in increased expenditures by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

Congressional Review Act

The Office of Government Ethics has determined that this amendatory rulemaking is a nonmajor rule under the Congressional Review Act (5 U.S.C. chapter 8) and will submit a report thereon to the U.S. Senate, House of Representatives and General Accounting Office in accordance with that law at the same time this rulemaking document is sent to the Office of the Federal Register for publication in the **Federal Register**.

Executive Order 12866

In promulgating these technical amendments, OGE has adhered to the regulatory philosophy and the applicable principles of regulation set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. These amendments have not been reviewed by the Office of Management and Budget under that Executive order, since they are not deemed "significant" thereunder.

Executive Order 12988

As Acting Director of the Office of Government Ethics, I have reviewed this final amendatory regulation in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects

5 CFR Part 2634

Certificates of divestiture, Conflict of interests, Financial disclosure, Government employees, Penalties, Privacy, Reporting and recordkeeping requirements, Trusts and trustees.

5 CFR Part 2635

Conflict of interests, Executive branch standards of ethical conduct, Government employees.

Approved: March 4, 2005.

Marilyn L. Glynn,

Acting Director, Office of Government Ethics.

■ For the reasons set forth in the preamble, the Office of Government Ethics is amending 5 CFR parts 2634 and 2635 as follows:

PART 2634—EXECUTIVE BRANCH FINANCIAL DISCLOSURE, QUALIFIED TRUSTS, AND CERTIFICATES OF DIVESTITURE

■ 1. The authority citation for part 2634 continues to read as follows:

Authority: 5 U.S.C. App. (Ethics in Government Act of 1978); 26 U.S.C. 1043; Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990), as amended by Sec. 31001, Pub. L. 104–134, 110 Stat. 1321 (Debt Collection Improvement Act of 1996); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

§ 2634.304 [Amended]

■ 2. Section 2634.304 is amended by:

■ a. Removing the dollar amount "$285" in paragraphs (a) and (b) and in example 1 following paragraph (d) and adding in its place in each instance the dollar amount "$305";

■ b. Removing the dollar amount "$114" in paragraph (d) and in examples 1 and 2 following paragraph (d) and adding in its place in each instance the dollar amount "$122"; and

■ c. Removing the dollar amount "$285" in examples 3 and 4 following paragraph (d) and adding in its place in each instance the dollar amount "$305".

PART 2635—STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE EXECUTIVE BRANCH

■ 3. The authority citation for part 2635 continues to read as follows:

Authority: 5 U.S.C. 7301, 7351, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

§ 2635.204 [Amended]

■ 4. Section 2635.204 is amended by:

■ a. Removing the dollar amount "$285" in paragraph (g)(2) and in examples 1 and 2 (in the latter of which it appears twice) following paragraph (g)(6) and adding in its place in each instance the dollar amount "$305"; and

■ b. Removing the dollar amount "$570" in example 2 following paragraph (g)(6) and adding in its place the dollar amount "$610".

[FR Doc. 05–4879 Filed 3–10–05; 8:45 am]

BILLING CODE 6345–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 94 and 95

[Docket No. 03–080–6]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Partial Delay of Applicability

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; partial delay of applicability.

SUMMARY: The amendments in this final rule delay until further notice the applicability of certain provisions of the rule entitled "Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities," published in the **Federal Register** on January 4, 2005, 70 FR 460–553. That rule was scheduled to amend the regulations in 9 CFR parts 93, 94, 95, and 96, effective March 7, 2005, to establish a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy into the United States via live ruminants and ruminant products and byproducts and to add Canada to this category. That rule included conditions for the importation of certain live ruminants and ruminant products from such regions.

DATES: Effective March 7, 2005.

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION: On January 4, 2005, we published a final rule in the **Federal Register** (70 FR 460–553, Docket No. 03–080–3) that establishes a category of regions that present a minimal risk of introducing

bovine spongiform encephalopathy into the United States via live ruminants and ruminant products and byproducts and that adds Canada to this category. The rule also establishes conditions for the importation of certain live ruminants and ruminant products from such regions. The rule was scheduled to become effective on March 7, 2005.[1]

Pursuant to an announcement by the Secretary of Agriculture on February 9, 2005, this document delays the applicability of the provisions in that rule as they apply to the importation from Canada of the following commodities when derived from bovines 30 months of age or older when slaughtered: (1) Meat, meat food products, and meat byproducts other than liver; [2] (2) whole or half carcasses; (3) offal; (4) tallow composed of less than 0.15 percent insoluble impurities that is not otherwise eligible for importation under 9 CFR 95.4(a)(1)(i); and (5) gelatin derived from bones of bovines that is not otherwise eligible for importation under 9 CFR 94.18(c).

If the courts allow the January 4, 2005, rule to go into effect while this delay of applicability is in effect, the commodities listed above that are derived from bovines less than 30 months of age when slaughtered must be accompanied to the United States by certification that (1) the age requirement has been met and (2) the commodity was processed in an establishment inspected by the Canadian Food Inspection Agency (CFIA) that operates in compliance with an approved CFIA program to prevent commingling of ruminant products eligible for export to the United States with ruminant products ineligible for export to the United States. Such certification must be made by a full-time salaried veterinary officer of Canada, or by a veterinarian designated and accredited by the Canadian Government, provided the certification is endorsed by a full-time salaried veterinary officer of Canada who represents that the veterinarian issuing the certification was authorized to do so.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the Department's implementation of this action without opportunity for public comment is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and 553(d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The delay of applicability is necessary to give Department officials the opportunity for further review and consideration of the specified provisions. Given the scheduled effective date of those provisions, seeking prior public comment on this delay would have been impractical, as well as contrary to the public interest, in the orderly promulgation and implementation of regulations.

[1] On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of APHIS' January 4, 2005, final rule is preliminarily enjoined.

[2] In accordance with an August 8, 2003, announcement by the Secretary of Agriculture, since August 2003 APHIS has issued permits for the importation into the United States from Canada of certain fresh or frozen liver from bovines of any age.

List of Subjects

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

■ Accordingly, we are amending 9 CFR parts 94 and 95 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE-FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 94.19 is amended by adding notes at the end of paragraphs (a), (b), and (f) to read as follows:

§ 94.19 Restrictions on importation from BSE minimal-risk regions of meat and edible products from ruminants.

* * * * *

(a) * * *

Note to paragraph (a): The applicability of paragraph (a) to meat, meat byproducts other than liver, and meat food products when such commodities are derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

(b) * * *

Note to paragraph (b): The applicability of paragraph (b) to whole or half carcasses derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * * * *

(f) * * *

Note to paragraph (f): The applicability of paragraph (f) to gelatin derived from the bones of bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * * * *

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

■ 3. The authority citation for part 95 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 4. Section 95.4 is amended by adding notes at the end of paragraphs (f) and (g) to read as follows:

§ 95.4 Restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy.

* * * * *

(f) * * *

Note to paragraph (f): The applicability of paragraph (f) to tallow derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

(g) * * *

Note to paragraph (g): The applicability of paragraph (g) to offal derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * * * *

Done in Washington, DC, this 8th day of March 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 05–4917 Filed 3–10–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19470; Directorate Identifier 2003–NM–268–AD; Amendment 39–13997; AD 2005–05–08]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100B SUD, –300, –400, and –400D Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

Federal Register

Wednesday,
July 14, 2004

Part III

Department of Agriculture

Animal and Plant Health Inspection Service

9 CFR Parts 50, 51, et al.

Food Safety and Inspection Service

9 CFR Parts 309, 310, 311, 318, and 319

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 589

Federal Measures To Mitigate BSE Risks: Considerations for Further Action; Proposed Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, and 85

[Docket No. 04–047–1]

RIN 0579–AB86

Food Safety and Inspection Service

9 CFR Parts 309, 310, 311, 318, and 319

[Docket No. 04–021ANPR]

RIN 0583–AC88

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 589

[Docket No. 2004N–0264]

RIN 0910–AF46

Federal Measures To Mitigate BSE Risks: Considerations for Further Action

AGENCIES: Animal and Plant Health Inspection Service and Food Safety and Inspection Service, USDA; and Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; invitation to comment.

SUMMARY: Following detection of bovine spongiform encephalopathy (BSE) in an imported dairy cow in Washington State in December 2003, the Secretaries of the U.S. Departments of Agriculture and Health and Human Services announced a series of regulatory actions and policy changes to strengthen protections against the spread of BSE in U.S. cattle and against human exposure to the BSE agent. The Secretary of Agriculture also convened an international panel of experts on BSE to review the U.S. response to the Washington case and make recommendations that could provide meaningful additional public or animal health benefits. The purpose of this advance notice of proposed rulemaking is to inform the public about the panel's recommendations and to solicit comment on additional measures under consideration based on those recommendations and other considerations.

DATES: APHIS and FSIS will consider all comments received on or before September 13, 2004. FDA will consider all comments received on or before August 13, 2004.

ADDRESSES:

You may submit comments to APHIS by any of the following methods:

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–047–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–047–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 04–047–1" on the subject line.
- Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS web site.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

You may submit comments to FSIS by any of the following methods:

- Mail, including floppy disks or CD–ROM's, and hand-or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov*. Follow the online instructions at that site for submitting comments.

Instructions: All submissions received must include the Agency name and Docket No. 04–021ANPR.

Other information: All comments submitted in response to this advance notice of proposed rulemaking, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/OPPDE/rdad/FRDockets.htm*.

You may submit comments to FDA by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency web site: *http://www.fda.gov/dockets/comments*. Follow the instructions for submitting comments.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0264 or Regulatory Identification No. (RIN) 0910–AF46 in the subject line of your e-mail message.
- Fax: (301) 827–6870.
- Mail/hand delivery/courier (for paper, disc, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions must include the Agency name and Docket No. 2004N–0264 or Regulatory Identification No. (RIN) 0910–AF46.

Other information: All comments received, including any personal information provided, will be posted without change to *http://www.fda.gov/dockets/ecomments*. For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

APHIS: Dr. Anne Goodman, Supervisory Staff Officer, Regionalization Evaluation Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

FSIS: Daniel L. Engeljohn, Ph.D., Deputy Assistant Administrator, Office of Policy, Program, and Education Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700, Telephone (202) 205–0495, Fax (202) 401–1760. Copies of references cited in this document are available in the FSIS Docket Clerk's Office (see **ADDRESSES**).

FDA: Burt Pritchett, D.V.M., Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7500

Standish Pl., Rockville, MD 20855, 301–827–0177, e-mail: *burt.pritchett@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Purpose

Bovine spongiform encephalopathy (BSE), widely referred to as "mad cow disease," is a progressive and fatal neurological disorder of cattle. The disease was first diagnosed in 1986 in the United Kingdom, but had never been detected in a native animal in North America until May 2003 when it was diagnosed in a single dairy cow in Canada. Subsequently, in December 2003, BSE was diagnosed in a single dairy cow in Washington State that had been imported from Canada. Variant Creutzfeld-Jakob disease, a chronic and fatal neurodegenerative disease that affects humans, has been linked to the consumption of beef products contaminated with the BSE agent. The U.S. Government—specifically, the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA)—has implemented a number of measures to protect the public from health risks associated with BSE and to prevent the spread of the disease in U.S. cattle. The agencies are currently considering additional safeguards based on the recommendations of an international review team convened by the Secretary of Agriculture and on other considerations. The purpose of this advance notice of proposed rulemaking (ANPRM) is to inform the public about the report and recommendations of the international review team and to solicit public comment on the additional measures under consideration.

II. Background

A. Bovine Spongiform Encephalopathy

BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). In addition to BSE, TSEs include, among other diseases, scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jakob disease (CJD) in humans. The agent that causes BSE and other TSEs has yet to be fully characterized. The theory that is most accepted in the scientific community is that the agent is a prion, which is an abnormal form of a normal protein known as cellular prion protein, although other agents have also been implicated. There is currently no test to detect the disease in a live animal. BSE is confirmed by postmortem microscopic examination of an animal's brain tissue or by detection of the abnormal form of the prion protein in an animal's tissues. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is extremely resistant to heat and to normal sterilization processes. It does not evoke any demonstrated immune response or inflammatory reaction in host animals.

Since November 1986, there have been more than 180,000 confirmed cases of BSE in cattle worldwide. The disease has been confirmed in native-born cattle in 22 European countries in addition to the United Kingdom, and in some non-European countries, including Japan, Israel, and Canada. Over 95 percent of all BSE cases have occurred in the United Kingdom, where the epidemic peaked in 1992/1993, with approximately 1,000 new cases in cattle reported per week. Agricultural officials in the United Kingdom have taken a series of actions to eliminate BSE, including making it a reportable disease, banning mammalian meat-and-bone meal in feed for all food-producing animals, prohibiting the inclusion of animals more than 30 months of age in the animal and human food chains, and destroying all animals showing signs of BSE and other potentially exposed animals at high risk of developing the disease. As a result of these actions, most notably the feed bans, the rate of newly reported cases of BSE in the United Kingdom has decreased sharply and continues a downward trend.

In 1996, a newly recognized form of the human disease CJD, referred to as variant CJD (vCJD), was reported in the United Kingdom. Scientific and epidemiological studies have linked vCJD to exposure to the BSE agent, most likely through human consumption of cattle products contaminated with the agent that causes BSE. To date, approximately 150 probable and confirmed cases of vCJD have been reported in the United Kingdom, where there had been a high level of consumption of contaminated cattle product. In the United States, where measures to prevent the introduction and spread of BSE have been in place for some time, there is far less potential for human exposure to the BSE agent. The Centers for Disease Control and Prevention (CDC) leads a surveillance system for vCJD in the United States, and as of December 2003, had not detected vCJD in any resident of the United States that had not lived in or traveled to the United Kingdom for extended periods of time. In 2002, a probable case of vCJD was reported in a Florida resident who had lived in the United Kingdom during the BSE epidemic. Epidemiological data indicate that the patient likely was exposed to the BSE agent before moving to the United States.

B. Prevention of BSE in the United States

The United States Government has implemented a number of measures since 1989 to prevent BSE from entering the United States and to prevent the spread of the disease should it be introduced into the United States.

Import Restrictions and 1997 Feed Ban

Since 1989, USDA's Animal and Plant Health Inspection Service (APHIS) has prohibited the importation of live cattle and other ruminants and certain ruminant products, including most rendered protein products, into the United States from countries where BSE is known to exist. In 1997, due to concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, APHIS extended importation restrictions on ruminants and ruminant products to all of the countries in Europe.

Also in 1997, HHS' Food and Drug Administration (FDA) prohibited the use of all mammalian protein, with the exception of pure pork and pure equine protein from single species processing plants, in animal feeds given to cattle and other ruminants (62 FR 30936; June 5, 1997; codified at 21 CFR 589.2000). The rule allows exceptions for certain products believed at the time to present a low risk of transmitting BSE: blood and blood products; gelatin; inspected meat products that have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings, referred to below as "plate waste"); and milk products (milk and milk protein). Firms must keep specified records on the manufacture of feed, have processes in place to prevent commingling of ruminant and nonruminant feed containing prohibited materials, and ensure that nonruminant feed containing materials prohibited in ruminant feed is labeled conspicuously with the statement, "Do not feed to cattle or other ruminants."

In December 2000, APHIS expanded its prohibitions on imports of rendered ruminant protein products from BSE-restricted regions to include rendered protein products of any animal species because of concern that cattle feed supposedly free of ruminant protein may have been cross contaminated with the BSE agent. FDA also issued import alerts on animal feed ingredients for APHIS-listed countries.

Animal Surveillance Program and Emergency Response Plan

The United States has had an active surveillance program for BSE since 1990. Historically, the sampling strategy was designed to detect one BSE-infected animal per million cattle and to take into account regional differences while striving for uniform surveillance throughout the country. Since 1993, BSE surveillance in the United States has met or exceeded international standards as outlined in the *Terrestrial Animal Health Code* of the Office International des Epizooties (OIE), the world organization for animal health. For additional details on BSE surveillance since 1990, see *http://www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html.*

Since its inception, animal surveillance for BSE in the United States has been designed to sample those cattle in which BSE is most likely to occur and in which the disease would most likely be detected. The targeted surveillance population has, therefore, included adult cattle displaying clinical signs that could be considered to be consistent with BSE. This includes cattle exhibiting signs of central nervous system (CNS) abnormalities, cattle that are non-ambulatory, cattle that have died on the farm from unexplained causes, and cattle that display other clinical signs that could be compatible with BSE. The BSE surveillance program has historically not included apparently healthy cattle presented for routine slaughter because that is not the population where the disease would most likely be detected.

Further, APHIS, in cooperation with USDA's Food Safety and Inspection Service (FSIS), prepared an emergency response plan to be used in the event that BSE is identified in the United States (*http://www.aphis.usda.gov/lpa/issues/bse/bsesum.pdf*). FDA and other Federal agencies have also developed contingency plans that would operate in association with the USDA plan. USDA and HHS have held various outreach and tabletop exercises to test various components of their contingency plans.

C. Risk of BSE in the United States

In April 1998, USDA contracted with the Harvard Center for Risk Analysis (HCRA) at Harvard University and the Center for Computational Epidemiology at Tuskegee University to conduct a comprehensive investigation of BSE risk in the United States. The report,[1] widely referred to as the Harvard Risk Assessment or the Harvard Study, is referred to in this document as the Harvard-Tuskegee Study. It was completed in 2001 and released by the USDA. Following a peer review of the Harvard-Tuskegee Study in 2002, the authors responded to the peer review comments and released a revised risk assessment in 2003.[2]

The Harvard-Tuskegee Study reviewed available scientific information related to BSE and other TSEs, assessed pathways by which BSE could potentially occur in the United States, and identified measures that could be taken to protect human and animal health in the United States. The assessment concluded that the United States is highly resistant to any proliferation of BSE or similar disease and that measures taken by the U.S. Government and industry make the United States robust against the spread of BSE to animals or humans should it be introduced into this country.

The Harvard-Tuskegee Study concluded that the most effective measures for reducing potential introduction and spread of BSE are: (1) The ban placed by APHIS on the importation of live ruminants and ruminant meat-and-bone meal from the United Kingdom since 1989 and all of Europe since 1997; and (2) the feed ban instituted in 1997 by FDA to prevent recycling of potentially infectious cattle tissue. The Harvard-Tuskegee Study further indicated that, if introduction of BSE had occurred via importation of live animals from the United Kingdom prior to 1989, mitigation measures already in place would have minimized exposure and begun to eliminate the disease from the cattle population.

The Harvard-Tuskegee Study also identified three pathways or practices that could facilitate human exposure to the BSE agent or the spread of BSE should it be introduced into the United States: (1) Non-compliance with FDA's ruminant feed regulations prohibiting the use of certain proteins in feed for cattle and other ruminants; (2) rendering of animals that die on the farm and use (through illegal diversion or cross contamination) of the rendered product in ruminant feed; and (3) the inclusion of high-risk tissues from cattle, such as brain and spinal cord, in products for human consumption. The Harvard-Tuskegee Study's independent evaluation of the potential risk mitigation measures predicts that a prohibition against rendering of animals that die on the farm would reduce the potential cases of BSE in cattle following hypothetical exposure by 82 percent as compared to the base case scenario,[3] and that a ban on specified risk materials (SRMs)[4], including brain, spinal cord and vertebral column, from inclusion in human and animal food would reduce potential BSE cases in cattle by 88 percent and potential human exposure to BSE by 95 percent as compared to the base case scenario.

In 2003, following the identification of BSE in a native-born cow in Canada, the HCRA evaluated the implications of a then hypothetical introduction of BSE into the United States[5], using the same simulation model developed for the initial Harvard-Tuskegee Study. This assessment confirmed the conclusions of the earlier study—namely, that the United States presents a very low risk of establishing or spreading BSE should it be introduced.

In May 2004, USDA contracted with the HCRA to revise and update the BSE risk assessment model to reflect recent events that have occurred in the United States. These recent events include such increased risk mitigation measures as the prohibition of SRMs in human food.

[1] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," *http://www.aphis.usda.gov/lpa/issues/bse/risk_assessment/mainreporttext.pdf*, 2001.

[2] Research Triangle Institute, "Review of the Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," accessed online at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_Peer_Review.pdf*, 2002. Harvard Center for Risk Analysis, Harvard School of Public Health, "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States: Response to Reviewer Comments Submitted by Research Triangle Institute," *http://www.aphis.usda.gov/lpa/issues/bse/ResponsetoComments.pdf*, 2003. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," *http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf*, 2003.

[3] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," section 3, "Simulation Model and Base Case Assumptions," *http://www.aphis.usda.gov/lpa/issues/bse/risk_assessment/mainreporttext.pdf*, 2001.

Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," *http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf*, 2003.

[4] Specified risk materials (SRMs) are ruminant tissues that have demonstrated infectivity at some point during the BSE incubation period.

[5] Harvard Center for Risk Analysis, Harvard School of Public Health, "Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada," accessed online at *http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf*, 2003.

In addition, USDA requested that the HCRA specifically analyze the recommendations of the international review team to determine whether the recommendations would provide significant differences in risk mitigation levels. While this information will be valuable as we analyze any future actions concerning domestic policy changes, the existing Harvard-Tuskegee model demonstrates that, with the safeguards in place—even before the case of BSE was detected in Washington State in December 2003—the risk of spread of BSE from any introduction was very low, due largely to import restrictions and the 1997 feed ban. Because control measures have been increased and strengthened since that time, it is anticipated that any changes to the model reflecting additional control measures would continue to demonstrate a further decrease in risk of spread.

III. The Case in Washington State and U.S. Actions in Response

On December 23, 2003, USDA announced a presumptive positive case of BSE in a dairy cow in Washington State. Samples had been taken from the cow on December 9 as part of USDA's BSE surveillance program. The BSE diagnosis was made on December 22 and 23 by histopathology and immunohistochemical testing at the National Veterinary Services Laboratories in Ames, IA, and verified on December 25 by the international reference laboratory, the Veterinary Laboratories Agency in Weybridge, England. This case followed the identification of BSE in a single cow in Alberta, Canada, in May 2003.

A. The Epidemiological Investigation and Related Activities

Upon detection of the BSE-positive cow in Washington State, USDA, FDA and other Federal and State agencies immediately began working together closely to perform a full epidemiological investigation [6], trace any potentially infected cattle, trace potentially contaminated rendered product, increase BSE surveillance, and take additional measures to address human and animal health.

The epidemiological investigation and DNA test results confirm that the infected cow was not indigenous to the United States, but rather was born and most likely became infected in Alberta, Canada, prior to Canada's 1997 implementation of a ban on feeding mammalian protein to ruminants.

The infected cow entered the United States on September 4, 2001, as part of a shipment of 81 animals from the source herd in Canada. Of these 81 animals, 25 were determined, as a result of the epidemiological investigation, to be higher risk as defined by the OIE. A higher risk animal is one born on premises known to be a source of an infected animal within 12 months before or after the birth of the infected cow.

Counting the infected cow, USDA definitively accounted for 14 of the 25 animals considered to be higher risk, along with 15 others from the source herd that were in the initial shipment, plus 7 additional animals dispersed from the birth herd. The number of animals found—35 in addition to the infected cow—is consistent with the number expected after analysis of regional culling rates.

In addition to those animals, another 220 cattle were culled from 10 premises on which one or more source herd animals were found. These cattle were culled because they could possibly have been from the Canadian source herd. Out of an abundance of caution, all 255 animals were euthanized and tested for BSE; all of the animals tested negative. Because there is a small probability that BSE can be transmitted maternally, the two live offspring of the infected cow were also euthanized. A third had died at birth in October 2001. All carcasses were properly disposed of in accordance with Federal, State, and local regulations.

In conjunction with USDA's investigation, FDA conducted an extensive feed investigation. By December 27, 2003, FDA had located all potentially infectious product rendered from the BSE-positive cow in Washington State. The product was disposed of in a landfill in accordance with Federal, State, and local regulations.

The United States concluded the active investigation and culling activities related to the one infected cow on February 9, 2004, and redirected resources toward planning, implementing, and enforcing national policy measures to promote BSE surveillance and protect human and animal health.

B. International Review Team Convened

Prior to the conclusion of the epidemiological investigation, on January 22–24, 2004, the Secretary of Agriculture convened an international panel of experts to assess the epidemiological investigation, provide expert opinion as to when the active phase should be terminated, consider the response actions of the United States to date, and provide recommendations as to actions that could be taken to provide additional meaningful human or animal health benefits in light of the North American experience.

The international review team was organized as a subcommittee of the Secretary of Agriculture's Foreign Animal and Poultry Disease Advisory Committee. The subcommittee consisted of Prof. U. Kihm (Switzerland), Prof. W. Hueston (USA), Dr. D. Matthews (UK), Prof. S. C. MacDiarmid (New Zealand), and Dr. D. Heim (Switzerland). The subcommittee (referred to below as the IRT) provided its report on February 4, 2004. The complete report, "*Report on Measures Relating to BSE in the United States*," is available for viewing at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_tr_ban_ltr%20_enc_2.pdf.*

In summary, the IRT was complimentary of the scope, thoroughness, and appropriateness of the epidemiological investigation and concluded that the investigation conformed to international standards. The review team members concurred that the investigation should be terminated. In addition, the IRT made several policy recommendations designed to further reduce the risk of cattle being exposed to BSE. These recommendations included several changes that the Federal Government had already embarked upon related to SRMs, non-ambulatory (downer) cows, surveillance, laboratory diagnosis, feed restrictions, traceability (*i.e.*, animal identification), education, control of implementation measures, and lessons learned. These Federal Government policies are discussed in the next section. A formal response to the IRT report, prepared collaboratively by USDA and FDA, may be viewed at *http://www.aphis.usda.gov/lpa/issues/bse/bse_responsetorep.pdf.*

C. Regulatory and Policy Actions

APHIS, FSIS, and FDA have taken additional steps to specifically address the potential pathways or practices that the Harvard-Tuskegee Study said could contribute most either to the spread of BSE in cattle or to human exposure to the BSE agent should BSE be introduced into the United States.

Safeguards on Food and Feed Supplies

FSIS, in a series of three interim final rules that were published and made effective on January 12, 2004, took additional measures to prevent the BSE agent from entering the human food supply. In its interim final rule titled,

[6] A report of the epidemiological investigation, "A Case of Bovine Spongiform Encephalopathy (BSE) in the United States," was issued in March 2004 and is available at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_tr_ban%20_ltr_enc_1.pdf.*

"Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (FSIS Docket No. 03–025IF; 69 FR 1861), and referred to below as the SRM rule, FSIS designated the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle as SRM, and prohibited their use as human food. To ensure effective removal of the distal ileum, the SRM rule requires establishments to remove the entire small intestine and dispose of it as inedible.

To facilitate the enforcement of the SRM rule, FSIS has developed procedures to verify the approximate age of cattle that are slaughtered in official establishments. Such procedures, based on records or examination of teeth, are intended to ensure that SRM from cattle 30 months of age and older are effectively segregated from edible materials.[7]

As provided by the SRM rule, materials designated as SRMs if they are from cattle 30 months of age and older will be deemed to be SRMs unless the establishment can demonstrate that they are from an animal that was younger than 30 months of age at the time of slaughter.

Furthermore, FSIS has developed procedures to verify that cross contamination of edible tissue with SRMs is reduced to the maximum extent practical in facilities that slaughter cattle, or process carcasses or parts of carcasses of cattle, both younger than 30 months of age and 30 months of age and older.[8] If an establishment uses dedicated equipment to cut through SRMs, or if it segregates cattle 30 months of age and older from cattle younger than 30 months of age, then the establishment may use routine operational sanitation procedures (*i.e.*, no special sanitation procedures are required). If the establishment doesn't segregate cattle 30 months of age and older from younger cattle, equipment used to cut through SRMs must be cleaned and sanitized before it is used on carcasses or parts from cattle less than 30 months of age. FSIS believes that, due to the multiple risk mitigation measures implemented in the United States to prevent the spread of BSE, these procedures will reduce to the maximum extent possible cross contamination of carcasses with high-risk tissues. However, to assist in determining whether it should strengthen the measures required of establishments, FSIS issued a press release during the comment period for the SRM rule that specifically requested public comment on methods to prevent cross contamination of carcasses with SRMs.[9]

The SRM rule also declared mechanically separated beef (MS(beef)) to be inedible and prohibited its use for human food. Additionally, the SRM rule prohibited all non-ambulatory disabled cattle for use as human food.

The second interim final rule, titled, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems' (FSIS Docket No. 03–038IF; 69 FR 1874–1885), prohibited products produced by advanced meat recovery (AMR) systems from being labeled as "meat" if, among other things, they contain CNS tissue. AMR is a technology that removes muscle tissue from the bone of beef carcasses under high pressure without incorporating significant amounts of bone and bone products into the final meat product. FSIS had previously established and enforced regulations that prohibited spinal cord from being included in products labeled "meat." This interim final rule expanded that prohibition to include dorsal root ganglia (DRG), clusters of cells connected to the spinal cord along the vertebral column. In addition, because the vertebral column and skull of cattle 30 months of age and older have been designated as SRM, they cannot be used for AMR. Because they are not SRMs, the skull and vertebral column from cattle younger than 30 months of age may be used in AMR systems. However, establishments that use skulls and vertebral columns in the production of beef AMR product must be able to demonstrate that such materials are from cattle younger than 30 months of age.

The third interim final rule, titled "Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter" (FSIS Docket No. 01–0331IF; 69 FR 1885–1891), prohibited the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle because they may force large fragments of CNS tissue into the circulatory system of stunned cattle where they may become lodged in edible tissues.

Also on January 12, 2004, FSIS published a notice announcing that it would no longer pass and apply the mark of inspection to carcasses and parts of cattle selected for BSE testing by APHIS until the sample is determined to be negative (FSIS Docket No. 03–048N; 69 FR 1892; "Bovine Spongiform Encephalopathy Surveillance Program").

FDA continues to conduct inspections to monitor compliance of feed mills, renderers, and protein blenders with the 1997 feed ban rule and is expanding the scope of its inspections to include other segments of animal feed production and use, such as transportation firms, farms that raise cattle, and animal feed salvage operations. Compliance by feed mills, renderers, and protein blenders with the feed ban is currently very high. Information on inspections and compliance is available at *http://www.fda.gov/cvm/index/bse/RuminantFeedInspections.htm.*

FDA, like FSIS, has taken additional measures to prevent the BSE agent from entering the human food supply. In an interim final rule published in the Rules and Regulations section of today's **Federal Register**, FDA prohibits SRMs, the small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and MS (beef) from use in FDA-regulated human food, including dietary supplements, and cosmetics (FDA Docket No. 2004N–0081; "Use of Materials Derived from Cattle in Human Food and Cosmetics").

This interim final rule on human food and cosmetics, as well as a second one related to animal feed, were announced by FDA on January 26, 2004. The interim final rule on animal feed was to remove the current exemptions in 21 CFR 589.2000 for blood and blood products and plate waste, prohibit the use of poultry litter in ruminant feed, and require equipment, facilities, or production lines to be dedicated to nonruminant animal feed if firms use protein that is prohibited in ruminant feed.

The IRT recommendations provide a different set of measures for reducing the risks associated with animal feed. The IRT approach is to prevent potentially infective tissues from ever entering animal feed channels. Although FDA believes the measures previously announced would serve to reduce the already small risk of BSE

[7] See FSIS Notice 05–04, "Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination," January 12, 2004, *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/rdad/fsisnotices/5-04.pdf*; and FSIS Notice 10–04, "Questions and Answers Regarding the Age Determination of Cattle and Sanitation," January 29, 2004, *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/rdad/fsisnotices/10-04.pdf*.

[8] See FSIS Notice 10–04.

[9] FSIS press release of March 31, 2004.

spread through animal feed, the broader measures recommended by the IRT, if implemented, could make some of the previously announced measures unnecessary. Either approach would require a significant change in current feed manufacturing practices. Therefore, FDA believes that additional information is needed to determine the best course of action in light of the IRT recommendations and has decided not to issue an interim final rule with the changes to the feed ban described in the January 26 announcement. Instead, FDA is requesting additional information through this ANPRM on the recommendations of the IRT, as well as on other measures under consideration to protect the animal feed supply.

The Federal Government has also taken additional significant nonregulatory actions in response to the detection of BSE in North America. These actions include enhancing surveillance for BSE; implementing a national animal identification system; enhancing laboratory diagnosis; and obtaining and providing guidance and strategies for the future.

Animal Surveillance

On March 15, 2004, Secretary of Agriculture Ann Veneman announced a one-time enhanced BSE surveillance plan, targeting cattle from populations considered at highest risk for BSE, as well as a sampling of animals from the clinically normal, aged cattle population (over 30 months as evidenced by the eruption of at least one of the second set of permanent incisors). The plan, implemented on June 1, 2004, incorporates recommendations from the IRT and the Harvard Center for Risk Analysis. Notably, the IRT has reviewed the surveillance plan and indicated that it is comprehensive and science-based, and that it addresses the important issues with regard to BSE surveillance in cattle.

Over a period of 12–18 months, APHIS will test as many cattle as possible in the targeted high-risk population. Data obtained in this effort will help determine the probable prevalence of BSE in the United States and whether risk management policies need to be adjusted. If at least 268,500 targeted high-risk animals are sampled, we will be able to detect BSE even if as few as 5 animals in this targeted population are positive. The key to surveillance is to look at the population of animals where the disease is likely to occur. Thus, if BSE is present in the U.S. cattle population, there is a significantly better chance of finding the BSE within this targeted high-risk cattle population than within the general cattle population.

In addition, FSIS public health veterinarians have begun assisting in APHIS' BSE animal surveillance efforts by collecting brain samples from all cattle condemned during ante-mortem inspection at federally inspected establishments. This allows APHIS to focus on sample collection at locations other than federally inspected establishments, such as rendering operations and farms.

APHIS ensured access to slaughterhouses and rendering plants for sample collection via a final rule published March 4, 2004 (APHIS Docket No. 99–017–3, 69 FR 10137, "Blood and Tissue Collection at Slaughtering and Rendering Establishments"). Samples may also be collected on the farm, at veterinary diagnostic laboratories, at public health laboratories, at veterinary clinics, sale barns, livestock auctions, etc.

Strengthening of the passive surveillance system for BSE through outreach and education is an integral part of the USDA surveillance plan. In this regard, APHIS has developed plans to enhance existing educational materials and processes in conjunction with other Federal and State agencies. These outreach efforts will inform veterinarians, producers, and affiliated industries of the USDA surveillance goals and the sometimes subtle clinical signs of BSE, and will encourage reporting of suspect or targeted cattle on farm and elsewhere. One of the tools for reporting high-risk cattle, announced on June 8, 2004, is a toll-free number (1–866–536–7593).

To help cover additional costs incurred by industries participating in the surveillance plan, and to help encourage reporting and collection of targeted samples, USDA may provide payments for certain transportation, disposal, cold storage, and other costs.

For a complete discussion of the enhanced BSE surveillance plan that will be carried out over the next 12–18 months, refer to APHIS' Bovine Spongiform Encephalopathy (BSE) Surveillance Plan of March 15, 2004 (available at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03–15–04.pdf*).

Laboratory Diagnosis

Testing of BSE surveillance samples is conducted at APHIS' National Veterinary Services Laboratories (NVSL) and at a participating network of State and Federal veterinary diagnostic laboratories throughout the continental United States. USDA has approved 12 geographically dispersed laboratories to assist with BSE surveillance.

USDA has also approved five rapid screening test kits and has provided funding for high-throughput laboratory equipment as necessary. The rapid screening test kits are commercially produced diagnostic test kits, intended for use in surveillance programs such as these. These kits are best used as screening tests—*i.e.*, they are very sensitive and are intended to identify anything that might possibly be positive. Each of the laboratories will use one or more of the rapid screening tests with the goal of having initial results available within 24 to 72 hours after the sample is collected.

NVSL remains the national reference laboratory for BSE. If any sample reacts on the initial screening test, the tissues will be immediately forwarded to NVSL for confirmatory testing. Samples with this type of initial reaction will be reported as inconclusives. Samples will only be determined to be negative or positive by NVSL using immunohistochemistry and/or western blot confirmatory testing. NVSL will also conduct quality assurance check testing and test a certain number of routine samples to ensure proficiency in conducting all approved rapid screening tests.

USDA will make public the number of tests conducted and the results on a periodic basis. Updates are available at *http://www.aphis.usda.gov/lpa/issues/bse-enhan_surv/bse_test_results.html.*

The United States Government encourages and supports the development of new diagnostic tests for BSE and other TSEs. USDA researchers regularly discuss advancements in this area with their counterparts throughout the world and will evaluate all scientific data submitted as part of an application for USDA approval of a diagnostic test.

Animal Identification (Traceability)

Animal disease outbreaks around the globe over the past decade and the detection of a BSE-positive cow in the United States in December 2003 have intensified public interest in developing a national animal identification program for the purpose of protecting animal health.

Having a system that can identify individual animals or groups, the premises where they are located, and the date of entry to each premises is fundamental to controlling any disease threat, foreign or domestic, to U.S. animal resources. Further, we must be able to retrieve this information in a timely manner after confirmation of disease outbreak in order to implement successful intervention strategies.

While there is currently no nationwide animal identification system in the United States for all animals of a given species, some segments of certain species are required to be identified as part of current APHIS disease eradication activities. In addition, some significant regional voluntary identification programs are in place, and others are currently being developed and tested.

USDA has defined several key objectives for a national system. These include: (1) Allowing producers, to the extent possible, the flexibility to use current systems or adopt new ones; (2) having a system that is technology neutral, so that all existing effective technologies and new technologies that may be developed in the future may be utilized; (3) having a system that builds upon national data standards to ensure that a uniform and compatible system evolves; (4) having a system that does not preclude producers from being able to use it with production management systems that respond to market incentives; and (5) designing the architecture so that the system does not unduly increase the role and size of the Government.

Design and implementation of such a national animal identification system are well under way (see *http://www.aphis.usda.gov/lpa/issues/nais/nais.html*). USDA is moving forward first on a voluntary basis, to integrate the various types of animal identification programs that currently exist in the United States, and then will scale up to the national level, to include those producers and animals that are not currently in an animal identification program. The goal is to create an effective, uniform, consistent, and efficient national system.

APHIS will initially fund cooperative agreements to help State and Tribal governments establish premises identification systems and to evaluate additional identification pilot projects that could also become a part of the overall animal identification system. Associations and other segments of the livestock industry may participate in State and Tribal projects. APHIS posted a request for proposals for these cooperative agreements in June and will accept applications until July 15, 2004. APHIS anticipates initiating projects funded through these cooperative agreements in August. USDA is currently conducting a series of listening sessions (June–August 2004) across the country, inviting public discussion on the national animal identification program.

Guidance and Strategy

The Federal Government has several existing mechanisms to ensure appropriate guidance and involvement from outside experts and interested stakeholders. The Secretary of Agriculture's Advisory Committee on Foreign Animal and Poultry Diseases (SACFAPD), which has 17 members from industry, States, and academia, advises the Secretary on program operations, measures to prevent the introduction of foreign animal diseases into the United States, and contingency measures should such a disease be introduced into the United States. This group meets regularly and can also solicit public and expert advice. In fact, the IRT was convened as a subcommittee of the SACFAPD. Similarly, FDA obtains guidance from outside experts through its Transmissible Spongiform Encephalopathy Advisory Committee (TSEAC). In addition, FDA's TSEAC includes a representative from APHIS.

The Federal Government also obtains guidance and advice from experts within the Government. USDA has an internal Transmissible Spongiform Encephalopathy (TSE) Working Group that provides scientific recommendations related to TSEs, including BSE. This technical group meets regularly and includes representatives from FSIS and USDA's Agricultural Research Service, as well as from HHS' Centers for Disease Control and Prevention, the National Institutes of Health, and FDA, and the Department of Defense, as needed. There is also a policy level Interagency TSE Working Group that provides support and advice.

Furthermore, USDA and HHS participate on international working groups set up to prevent the spread of BSE to new areas of the world and to standardize approaches for addressing BSE surveillance and response. USDA and HHS participate in OIE meetings as members and consultants, and U.S. representatives offer technical advice on BSE-related issues and uphold U.S. interests in the World Health Organization and the Pan American Health Organization as well. Since 1986, the United States has exchanged scientists with several European countries, and U.S. officials have historically and routinely met with their counterparts in many countries on animal health risk mitigation measures. A standing North American Animal Health Committee that includes chief veterinary officers from Canada, Mexico, and the United States has developed and is working to implement a North American BSE strategy. After the finding of the BSE-positive cow in Canada in May 2003, U.S., Canadian, and Mexican officials sent a letter to the OIE regarding a scientific approach to BSE and trade issues. The United States has also taken a leadership role by proposing a new "minimal risk" BSE classification and criteria for trade in low-risk products for countries with established mitigation measures and a low incidence of BSE (APHIS Docket No. 03–080–1; 68 FR 62386–62405; November 4, 2003: "Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities").

IV. OIE Standards

As recognized in the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") under the auspices of the World Trade Organization ("WTO"), the OIE is the relevant international organization responsible for development and periodic review of standards, guidelines, and recommendations with respect to animal health and zoonoses (diseases that are transmissible from animals to humans). The OIE criteria for terrestrial animals (mammals, birds, and bees) are detailed in the *Terrestrial Animal Health Code* (available on the OIE Web site at *http://www.oie.int*).

Chapter 2.3.13 of the *Terrestrial Animal Health Code* describes the OIE standards with regard to BSE and is supplemented by Appendix 3.8.4 on surveillance and monitoring systems for BSE. The OIE standards for diagnostic tests with regard to BSE are described in Chapter 2.3.13 of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. However, the OIE standards are constantly evolving and are subject to change in response to new scientific findings and perspectives.

The current OIE standards contain criteria for establishing the BSE risk status of a country or zone. Under the current standards, the BSE-risk status of a country or zone is determined on the basis of a risk assessment identifying all potential factors for BSE occurrence and their historic perspective; an assessment of the likelihood that a TSE agent has been introduced via the importation of potentially contaminated animals or commodities (*i.e.*, meat-and-bone meal or greaves (the protein-containing residue obtained after the partial separation of fat and waste during the process of rendering), live animals, animal feed and feed ingredients, and products of animal origin for human consumption); and an assessment of the likelihood of exposure of the BSE agent to cattle, based on a consideration of a number of criteria, including the

existence and duration of a feed ban and BSE surveillance and monitoring programs. In addition, risk status levels are based on the length of time for demonstrated compliance with these criteria and on the reporting of BSE cases or BSE incidence rate.

To increase the likelihood of detecting BSE, the OIE recommends surveillance targeting cattle displaying clinical signs compatible with BSE and cattle that have died or been killed for reasons other than routine slaughter. In countries or zones not free of BSE, the OIE recommends routine sampling at slaughter. Surveillance should focus primarily on cattle over 30 months of age. The OIE also recommends a minimum number of samples to be taken from the targeted population for effective surveillance, based on the total cattle population over 30 months of age.

The OIE currently specifies five BSE status levels for countries or zones: Free, provisionally free, minimal risk, moderate risk, and high risk. The purpose of the categorization system is to enable and encourage appropriate risk mitigation measures to be applied to commodities for trade.

The OIE also sets international standards for trade in live cattle, fresh meat and meat products, gelatin and collagen prepared from bones, tallow and tallow derivatives, and dicalcium phosphate, according to the BSE risk status of a country or zone. In order to protect public and animal health, the OIE currently recommends different risk mitigating measures, with increased requirements as the status of a country or zone moves from lower to higher levels of BSE risk. The present OIE Code does not suggest a total embargo of animals and animal products coming from BSE affected countries, not even from countries considered as having high BSE risk, as long as the proper risk mitigation measures are applied.

The OIE also identifies certain commodities that should not require any BSE-related restrictions, regardless of the BSE status of the exporting country or zone. For example, the *Terrestrial Animal Health Code* does not recommend any restrictions, regardless of the BSE status of the country, in trade of semen, embryos, milk, milk products, and gelatin and collagen coming from hides and skins because these products or tissues have not demonstrated BSE infectivity in cattle.

The actions taken by the U.S. Government to prevent the introduction and spread of BSE in the United States are generally consistent with international standards for BSE, although not in all cases exactly the same. For example, U.S. surveillance for BSE in cattle has exceeded the OIE standards since 1993. Based on an adult cattle population of approximately 40 million, the OIE standard (Terrestrial Animal Health Code Appendix 3.8.4) calls for a minimum of 433 samples. By comparison, the United States has increased the number of samples from approximately 700 in fiscal year 1993 to approximately 20,000 in fiscal year 2002.

USDA appreciates the significant contributions of the OIE to science-based understanding of the true BSE-related risks in international trade and will continue to work with the OIE and other relevant international organizations. The United States is also taking a leadership role by proposing criteria for low-risk product trade with countries that have a low incidence of BSE and historically strong risk mitigation measures, mentioned previously in this document in section III, *The Case in Washington State and U.S. Actions in Response*, under *Guidance and Strategy*.

V. Recommendations of the IRT and Additional Measures for Consideration

A. Response Actions

In its general remarks about actions taken by the United States in response to the case of BSE in Washington State, the IRT, under "Response actions," recommended that policy actions under consideration by the United States achieve the following objectives:

- Reduce public health risk for consumer protection.
- Limit recycling and amplification of the agent.
- Establish the level of effectiveness of measures through surveillance.
- Prevent any inadvertent introduction of BSE from abroad in the future.
- Contribute to the prevention of the spread of the epidemic worldwide [p. 3].

The IRT report further stated:

> To achieve the above objectives, a system of complementary barriers, and implementation and enforcement of all measures on the national level, is necessary.
>
> The objectives cannot be successfully achieved by government alone; effective implementation of measures requires a shared commitment and action on the part of national and state governments, producers, consumers, private industry, and veterinary professionals. Extensive national coordination and cooperation is imperative, and should be extended to include the continent of North America. We suggest that a BSE task force, which includes governmental and non governmental stakeholders, is established under the leadership of the USDA in order to assure that policies are developed and implemented in a consistent, scientifically valid manner. [p. 3]

As noted earlier in section III, *The Case in Washington State and U.S. Actions in Response*, under *Guidance and Strategy*, both the Secretary of Agriculture and the Commissioner of FDA have advisory committees, which include both governmental and nongovernmental stakeholders, to provide guidance on issues concerning BSE and other TSEs. There are also technical and policy level interagency working groups on TSEs.

USDA welcomes comment on the following question:

1. Would there be value in establishing a specialized advisory committee or standing subcommittee on BSE?

The IRT also evaluated actions taken by the U.S. Government in response to the confirmation of the case of BSE in the United States and made recommendations regarding further actions that could provide additional public or animal health benefits. We are requesting public comment below on additional measures we are considering based on the IRT's recommendations. Because we believe that prior actions taken by the Federal Government already address IRT recommendations related to surveillance, laboratory diagnosis, non-ambulatory (downer) cattle, and certain other recommendations (*e.g.*, concerning the mechanical removal of bone from beef) (see the discussions in section III, *The Case in Washington State and U.S. Actions in Response*), we are not specifically requesting comment on those recommendations.

B. The Human Food Supply

In the section of the IRT report headed, "Specified Risk Materials (SRM)," the IRT stated:

> Unless aggressive surveillance proves the BSE risk in the USA to be minimal according to OIE standards, the [IRT] recommends that the SRM identified below be excluded from both the human and animal food chains.
>
> - Brain and spinal cord of all cattle over 12 months of age.
> - Skull and vertebral column of cattle over 12 months of age—these are not inherently infected, but cannot be separated from dorsal root/trigeminal ganglia or from residual contamination with CNS tissue.
> - Intestine—from pylorus to anus—from all cattle.
>
> In the mean time, until the level of BSE risk has been established, the [IRT] concedes that exclusion of CNS, skull, and vertebral column from cattle over 30 months, and intestines from cattle of all ages, for use in human food is a reasonable temporary compromise. [pp. 3–4]

USDA has initiated an aggressive and comprehensive surveillance program that will assist in estimating the prevalence of BSE in the United States and provide a basis for further assessments of whether and how U.S. actions related to BSE should be adjusted. Also, FSIS and FDA require the exclusion of CNS tissue, skull, and vertebral column from cattle 30 months of age and older, and the small intestine and tonsils from cattle of all ages, from human food, including dietary supplements, and cosmetics.

With regard to the age of cattle from which SRMs should be removed, FSIS and FDA have specified that CNS tissue, skull and vertebral column should be removed from cattle 30 months of age and older. Research to date indicates that 30 months is the appropriate threshold for removal of these materials unless surveillance indicates that there is a high prevalence of BSE in the U.S. cattle population, which the agencies believe is unlikely because of the feed and import restrictions that the Federal Government has imposed. The reason that age matters at all is that levels of infectious agent in certain tissues vary with the age of animal. Pathogenesis studies, where tissues obtained from orally infected calves were assayed for infectivity, have shown that infectivity was not detected in most tissues until at least 32 months post-exposure.[10] The exception to this is the distal ileum, the distal portion of the small intestine, where infectivity was confirmed from experimentally infected animals as early as 6 months post-exposure and tonsils, where infectivity was confirmed at 10 months post-exposure.

Although a few cases of BSE have been found in cattle under 30 months of age, research demonstrates that the shorter incubation period (*i.e.*, infection developing in less than 30 months) is apparently linked to younger animals receiving a relatively large infectious dose.[11] The younger cases have occurred primarily in countries with significant levels of circulating infectivity. Specifically, BSE has been found in animals less than 30 months of age in the United Kingdom in the late 1980s to early 1990s, when the incidence of BSE was extremely high. This research also suggests that a calf must receive an oral dose of 100 grams of infected brain material containing high levels of the infectious agent to produce disease within a minimum of approximately 30 months.[12]

BSE testing in the European Union (EU) was conducted throughout the year 2001. This testing revealed only two positive animals that were younger than 30 months of age in a total of 2,147 positive cases. Of note is that these animals were 28 and 29 months of age. For reference, in 2001, a total of 8,516,227 tests were conducted within the EU, and, of those, 1,366,243 tests were conducted on animals less than 30 months of age. In 2002, there were no animals less than 30 months of age that were positive in the EU testing scheme. Approximately 10.2 million tests were conducted in EU Member States in 2002, and, of these, 1.6 million were conducted on animals less than 30 months of age. The average mean age of positive animals in the EU in 2002 was 96.9 months, an increase from 85.9 months in 2001.[13]

This suggests an effective and prudent dividing line for purposes of mitigating risk. Infected cattle over 30 months of age may have levels of the abnormal prion in affected tissues that are sufficient to infect other animals fed protein derived from these tissues. Infected cattle younger than 30 months of age are unlikely to have infectious levels of the prion protein.[14] The 30-month age limit is accepted internationally in BSE standards set by various countries and is consistent with OIE recommendations.

With respect to the IRT recommendation that the entire intestine from cattle of all ages should be excluded from the human and animal food chains, FSIS noted in its SRM rule that BSE infectivity has only been confirmed in the distal ileum of the small intestine. FSIS requires the entire small intestine to be removed and disposed of as inedible to ensure effective removal of the distal ileum. Consistent with USDA's restrictions, FDA prohibits the use of the small intestine in FDA-regulated human food and cosmetics.

Note: The aspect of this recommendation pertaining to removal of SRMs from animal feed is addressed below under "Animal Feed Restrictions.")

FSIS and FDA request comment, especially scientific information, on the following question:

2. What data or scientific information is available to evaluate the IRT recommendation described above, including that aspect of the recommendation concerning what portion of the intestine should be removed to prevent potentially infective material from entering the human food and animal feed chains?

C. Animal Feed Restrictions

Specified Risk Materials (SRMs)

In the "Feed Restrictions" section of the report, the IRT recommended: "All SRM should be excluded from all animal feed, including pet food." [p. 5] FDA has prohibited the use of most mammalian proteins in ruminant feed since 1997. The IRT report stated that, "Considering the BSE situation in North America, the [IRT] believes the partial (ruminant to ruminant) feed ban that is currently in place is insufficient to prevent exposure of cattle to the BSE agent." [p. 5] The IRT further stated that, "While science would support the feed bans limited to the prohibition of ruminant derived [meat and bone meal] MBM in ruminant feed, practical difficulties of enforcement demand more pragmatic and effective solutions." [p. 6] Specifically, the IRT cited epidemiological evidence in the United Kingdom that highlight the dangers of cattle infection through the consumption of feed that had been contaminated accidentally when manufactured in premises that legitimately used mammalian meat and bone meal in feed for pigs and poultry. [p. 5] In addition, the IRT report cited an ongoing attack rate study at the Veterinary Laboratories Agency in the United Kingdom that demonstrates

[10] Wells, G.A.H., *et al.* 1994. Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy. Veterinary Record. 135 (2): 40–41.

Wells, G.A.H., *et al.* 1998. Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): An update. Veterinary Record. 142: 103–106.

European Union Scientific Steering Committee (EU SSC). 2002. Update of the opinion on TSE infectivity distribution in ruminant tissues (initially adopted by the Scientific Steering Committee at its meeting of 10–11 January 2002 and amended at its meeting of 7–8 November 2002) following the submission of (1) a risk assessment by the German Federal Ministry of Consumer Protection, Food, and Agriculture and (2) new scientific evidence regarding BSE infectivity distribution in tonsils; European Commission, Scientific Steering Committee, Health and Consumer Protection Directorate General; *http://www.europa.eu.int/comm./food/fs/sc/ssc/outcome_en.pdf.*

[11] EU SSC 2002 (see footnote 9).

[12] EU SSC 2002 (see footnote 9).

Department for Environment, Food and Rural Affairs (DEFRA), U.K., 2003; DEFRA BSE information, *http://www.defra.gov.uk/animalh/bse/index.htm.*

[13] European Commission (EC), 2002; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2001, European Commission Health and Consumer Protection Directorate-General; *http://europa.eu.int/comm/food/fs/bse/bse45_en.pdf.*

European Commission (EC), 2003; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2002, European Commission Health and Consumer Protection Directorate-General; *http://europa.eu.int/comm/food/fs/bse/testing/annual_%20report_2002_en.pdf.*

[14] Wells, *et al.*, 1994; Wells, *et al.*, 1998; EU SSC 2002 (see footnote 9).

transmission of BSE with 10 mg of infectious brain tissue. [p. 5] Although not yet published, more recent results from this study have demonstrated transmission with a lower dose of infectious brain tissue. These levels are significantly lower than the 1 gram infectious dose that had been demonstrated in the same study at the time the 1997 BSE feed rule was issued. Further, the Harvard-Tuskegee Study showed that removing SRMs from all animal feed reduces by 88 percent the potential exposure of cattle to the BSE agent when 10 BSE infected cattle are introduced into the United States. Accordingly, FDA has tentatively concluded that it should propose removing SRMs from all animal feed to adequately control the risks associated with cross contamination throughout feed manufacture and distribution and with intentional or unintentional misfeeding on the farm. FDA is currently working on a proposal to accomplish this goal.

To assist FDA in completing that proposal, FDA seeks comment on the following questions:

3. What information, especially scientific data, is available to support or refute the assertion that removing SRMs from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of feeding errors on the farm? What information is available on the occurrence of on-farm feeding errors or cross-contamination of ruminant feed with prohibited material?

4. If SRMs are prohibited from animal feed, should the list of SRMs be the same list as for human food? What information is available to support having two different lists?

5. What methods are available for verifying that a feed or feed ingredient does not contain SRMs?

6. If SRMs are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross-contamination between SRM-free rendered material and material rendered from SRMs?

7. What would be the economic and environmental impacts of prohibiting SRMs from use in all animal feed?

8. What data are available on the extent of direct human exposure (contact, ingestion) to animal feed, including pet food? To the degree such exposure may occur, is it a relevant concern for supporting SRM removal from all animal feed?

Cross Contamination

The "Feed restrictions" section of the IRT report also stated:

> Cross contamination must be prevented throughout the feed chain, from reception and transportation of feed ingredients, during the manufacturing process, through transportation and storage of finished feed, and on farm where mixing, blending, and feeding will occur. [p. 6]

The 1997 feed rule required manufacturers and distributors that handle both prohibited and nonprohibited material to control cross contamination by either: (1) Maintaining separate equipment or facilities; or (2) using clean-out procedures or other means adequate to prevent carry-over of prohibited material into feed for ruminant animals. In response to the finding of a BSE-positive cow in Washington State, FDA announced its intention to strengthen measures to prevent cross contamination by requiring dedicated equipment or facilities. However, in light of the IRT's recommendations, if SRMs are prohibited in all animal feed, dedicated facilities may no longer be necessary to reduce the risk associated with cross contamination. Therefore, FDA is reevaluating the need for requiring dedicated facilities.

FDA seeks comment on the following questions:

9. What information, especially scientific data, is available to show that dedicated facilities, equipment, storage, and transportation are necessary to ensure that cross contamination is prevented? If FDA were to prohibit SRMs from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage, and transportation? If so, what would be the scientific basis for such a prohibition?

10. What would be the economic and environmental impacts of requiring dedicated facilities, equipment, storage, and transportation?

11. What information, especially scientific data, is available to demonstrate that clean-out would provide adequate protection against cross contamination if SRMs are excluded from all animal feed?

All Mammalian and Avian Protein

As reported in the "Feed restrictions" section of the IRT report:

> The [IRT] recommends that the current feed ban be extended to exclude all mammalian and poultry protein from all ruminant feeds, and that this ban as well as measures to prevent cross contamination be strongly enforced. This recommendation must be enforced through an inspection program including sampling and testing of feed. [p. 6]

As noted previously, although the IRT agreed that "science would support the feed bans limited to the prohibition of ruminant derived MBM in ruminant feed," the IRT stated that "practical difficulties of enforcement demand more pragmatic and effective solutions." [p. 6] In particular, the IRT said:

> The prohibition of the use of all MBM (including avian) in ruminant feed is justified partly due to the issues of cross contamination as well as the current problems in differentiating mammalian and avian MBM. It also prevents the inclusion of ruminant derived protein contained within the lumen of porcine or avian intestines at slaughter in animal feed that may be used for ruminants. [p. 6]

Although the IRT discussed the problems with rendered MBM, the IRT report did not specifically address the potential risks from other mammalian and avian protein, such as milk, blood, gelatin, and tallow (rendered fat) that may contain small amounts of protein. The 1997 final rule, which banned the use of most mammalian protein in ruminant feed, did not include these materials in the definition of animal proteins prohibited in ruminant feed because they were not considered to pose a risk of BSE transmission. Prior to release of the IRT recommendations, FDA had announced its intentions to eliminate exemptions in the current ruminant feed rule for blood and blood products and plate waste, and to prohibit the practice of incorporating poultry litter into ruminant feed. FDA is now evaluating whether the announced measures need to be modified in light of the IRT recommendations. With respect to tallow, the OIE categorizes tallow with a maximum level of insoluble impurities of 0.15 percent as protein-free tallow and recommends that tallow that meets this standard be freely traded regardless of the BSE status of the country of origin.

FDA seeks comment on the following questions:

12. What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

13. If SRMs are required to be removed from all animal feed, what information, especially scientific data, is available to support the necessity to also prohibit all mammalian and avian MBM from ruminant feed, or to otherwise amend the existing ruminant feed rule?

14. What would be the economic and environmental impacts of prohibiting all mammalian and avian MBM from ruminant feed?

15. Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants?

16. What information is available to show that plate waste poses a risk of BSE transmission in cattle and other ruminants?

17. If FDA were to prohibit SRMs from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed? If so, what would be the scientific basis for such a prohibition?

18. What would be the economic and environmental impacts of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed?

19. Is there any information, especially scientific data, showing that tallow derived from the rendering of SRMs, dead stock, and non-ambulatory disabled cattle poses a significant risk of BSE transmission if the insoluble impurities level in the tallow is less than 0.15 percent?

Non-Ambulatory (Downer) Cattle

In the "Non-ambulatory (downer) cows" section of the report, the IRT noted the need to prevent potentially infective tissues from entering the feed chain. [p. 4] In addition to downer cattle, FDA is concerned about cattle that die on the farm or are killed for humane reasons (*i.e.*, dead stock) because they are also among the highest risk cattle population. Furthermore, little, if any, infrastructure is in place for removal of SRMs from cattle that are not slaughtered as part of the routine process that occurs at government inspected slaughter establishments. As previously discussed, the Harvard-Tuskegee Study showed that prohibiting rendering of animals that die on the farm would reduce the potential cases of BSE following hypothetical exposure by a further 82 percent from the base case scenario. Thus, FDA is evaluating the need to prohibit materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.

FDA seeks comment on the following questions:

20. Can SRMs be effectively removed from dead stock and non-ambulatory disabled cattle so that the remaining materials can be used in animal feed, or is it necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled cattle from use in all animal feed?

21. What methods are available for verifying that a feed or feed ingredient does not contain materials from dead stock and non-ambulatory disabled cattle?

22. What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory disabled cattle from use in all animal feed?

Disposal of SRMs and Non-Ambulatory Disabled Cattle

Additionally, in the "Feed restrictions" section of the report, the IRT stated:

> Recognising the absence of an established infrastructure for the separation and disposal of SRM or MBM the subcommittee accepted that a staged approach may be necessary for implementation. Exclusion and destruction of such a high volume of raw material is a massive burden on all countries currently affected by BSE. Given the susceptibility of cattle to low dose exposure, and the fact that no processing system exists at present to guarantee destruction of infectivity in commercial processes, it is probable that restoration of traditional uses in feed may be impossible. More radical and innovative solutions are required to enable the safe use of such materials in future. This should include adding value through their use for purposes other than the manufacture of feed and fertilisers (*e.g.* as a fuel source.) [p. 6]

USDA's Rural Business-Cooperative Service announced on May 18, 2004, a pilot project to provide guaranteed loans to rural small businesses for developing renewable energy systems primarily through use of specified risk materials, non-ambulatory cattle, or other cattle deemed to be at risk of carrying BSE (69 FR 28111–29119). Applications must be received by August 16, 2004.

APHIS welcomes comment on the following question:

23. What other innovative solutions could be explored?

D. Animal Identification (Traceability)

In the section of the IRT report headed, "Traceability," the IRT acknowledged that the U.S. Government has "recognized the importance of effective identification and traceability systems, that have value not only for the cost-effective and rapid tracing of animals for culling, but also for containment of contagious diseases." [p. 6] The IRT "encourages the implementation of a national identification system that is appropriate to North American farming." [p. 6]

As discussed in section III, *The Case in Washington State and U.S. Actions in Response*, under *Animal Identification (Traceability)*, APHIS is implementing a national animal identification system.

The national animal identification system will allow the Federal Government to trace back and trace forward animals potentially exposed to a disease of concern. Traceback refers to the ability to track an animal's location over its lifespan and the ability to determine which animals may have been in contact with the diseased animal or shared a contaminated feed supply. Trace forward data provides locations of animals moved out of the premises of concern that may have been exposed to the disease. When fully implemented, the national animal identification system calls for a trace to be completed within 48 hours of detecting a disease, thereby helping to contain an outbreak. The ability to achieve the 48-hour goal is directly related to the completeness of animal movement data that is reported to the national system. Developing and establishing all components of this national system present significant challenges.

APHIS recognizes the need to be able to ensure that data provided by producers is protected, and that all components of the system are in place and have been tested, before making the system mandatory. APHIS also recognizes that market forces will affect producer involvement (*e.g.*, some establishments may begin to accept only animals that are identified under the national system).

APHIS invites comment on the following questions:

24. When and under what circumstances should the program transition from voluntary to mandatory?

25. What species should be covered, both initially and in the longer term? Specifically, should the initial emphasis be on cattle, or also cover other species? If so which? Which species should be covered by the program when it is fully implemented? What priority should be given to including different species?

E. Education

In the section of the IRT report headed, "Education," the IRT stated:

> BSE educational programs must be designed to meet the needs of multiple audiences with variable levels of scientific training. Countries around the world have routinely underestimated the need for a wide variety of educational materials and training techniques to meet both technical and non-technical audiences. The [IRT] recommends that extensive education and training materials be developed in collaboration with academic, professional, trade and consumer organizations so that scientifically sound and accurate information about the nature of BSE and the importance of aggressive prevention and control strategies can be disseminated widely and incorporated into the curricula of schools, college, universities and professional continuing education programs. As traceability, transparency and access to current information increases, so does consumer confidence and effectiveness of the control and prevention measures. [pp. 6–7]

FDA, FSIS, and APHIS continue to develop educational and training materials. BSE became a reportable

disease in the United States in 1986. In May 1990, USDA began educational outreach to veterinarians, cattle producers, and laboratory diagnosticians regarding the clinical signs and diagnosis of BSE. These activities have been broadened both in terms or scope and targeted audiences in recent years, to include awareness programs for personnel involved in the transportation, marketing, and slaughter of cattle, as well as the general public, through various means, including frequent briefings and press conferences, fact sheets, videotapes, and information on its web site. FDA has conducted training for Federal and State investigators conducting inspections of feed mills, rendering establishments, and other regulated facilities, developed educational materials, including a CD, for investigators and the industry on the inspection process, developed guidance documents for each of the industry segments affected by the regulations, available on the Internet and in Spanish; and collaborated with industry organizations to develop educational materials for specific audiences.

All three agencies welcome comment on the following questions:

26. How can training and educational materials be designed or improved to meet the needs of multiple audiences with variable levels of scientific training?

27. How can the Federal Government increase access to these materials?

VI. Other Considerations

A. Animal Feed Measures

FDA believes it is necessary to consider the current state of technology when developing new requirements for animal feeds. The IRT report cites the limitations of sampling techniques and test sensitivity as the rationale, in part, for why further restrictions are needed to prevent cross contamination. The IRT noted:

> If at some point it becomes possible through other means (*e.g.*, inspection, testing, and enforcement) to achieve the equivalent result of assuring that no ruminant proteins are ingested by ruminants, then exclusion of all mammalian protein from feed for ruminants may not be required.

FDA is interested in the impact of technology development on all possible new requirements and seeks comment on the following questions:

28. Should FDA include exemptions to any new requirements to take into account the future development of new technologies or test methods that would establish that feed does not present a risk of BSE to ruminants?

29. If so, what process should FDA use to determine that the technologies or test methods are practical for use by the feed industry and ruminant feeders and provide scientifically valid and reliable results?

B. FDA Authority

FDA requests comments on the following questions:

30. Do FDA's existing authorities under the Federal Food, Drug, and Cosmetic Act (that address food adulteration and misbranding) and under the Public Health Service Act (that address the prevention and spread of communicable diseases) provide a legal basis to ban the use of SRMs and other cattle material in nonruminant animal feed (*e.g.*, feed for horses, pigs, poultry, etc.) notwithstanding that such materials have not been shown to pose a direct risk to nonruminant animals? More specifically, under FDA's existing legal authorities, would the potential occurrence of on-farm feeding errors, of cross contamination of ruminant feed with SRMs and other cattle material, or of human exposure to nonruminant feed (including pet food) provide a basis to ban SRMs and other cattle material from all animal feed?

31. Are there other, related legal issues on which FDA should focus?

C. Sanitation and Cross Contamination

As discussed in section III, *The Case in Washington State and U.S. Actions in Response*, under *Safeguards on Food and Feed Supplies*, to ensure that that establishments that slaughter or process cattle that are 30 months of age or older, as well as cattle that are younger than 30 months of age, are taking appropriate actions to prevent contamination of edible carcasses and parts with SRMs, FSIS has developed procedures for its inspection program personnel to verify that the equipment (*e.g.*, saws and knives) is properly cleaned and sanitized between carcasses or parts. FSIS also issued a press release during the comment period for its SRM rule to specifically solicit public comment on methods used to prevent cross contamination of carcasses with SRMs. One comment has suggested that FSIS require dedicated equipment for the removal and severing of SRMs, noting that the Canadian Food Inspection Agency requires that Canadian establishments use dedicated knives to sever the spinal cord of cattle 30 months of age and older. Also, because cattle infected with BSE are more likely to contain infectious levels of the BSE agent if they are 30 months of age and older, equipment that comes in contact with SRMs exclusively from cattle 30 months of age and older could potentially become contaminated with high levels of the BSE agent and come in contact with edible tissue. Therefore, FSIS is evaluating the need for additional sanitation requirements to prevent cross contamination of edible portions of carcasses with SRMs in establishments that predominantly slaughter cattle 30 months of age and older.

FSIS welcomes comment, especially scientific information, on the following questions:

32. What measures are necessary to prevent cross contamination between carcasses?

33. In establishments that predominantly slaughter cattle 30 months of age and older. are additional sanitation requirements necessary to prevent edible portions of carcasses from being contaminated with SRMs?

D. Equivalence

In response to the FSIS rule that prohibits SRMs and non-ambulatory disabled cattle for use in human food, FSIS has received several comments from countries that consider themselves "BSE free" requesting that the Agency exempt countries recognized as "BSE free" or "provisionally free" from the requirements of the interim final rule. According to these countries, their BSE status provides the same level of protection against BSE that is achieved domestically by the provisions in the FSIS interim final rule. Therefore, these countries assert that their BSE status is an "equivalent sanitary measure."

Meat and meat products exported to the United States from another nation must meet all sanitary standards applied to meat and meat products produced in the United States. The United States makes determinations of equivalence by evaluating whether foreign food regulatory systems attain the appropriate level of protection provided by our domestic system. Thus, while foreign food regulatory systems need not be identical to the U.S. system, they must employ equivalent sanitary measures that provide the same level of protection against food safety hazards as achieved domestically.

Currently, the prohibition on the use of materials designated as SRMs in FSIS" SRM rule applies to all such materials, regardless of the BSE status of the country of origin, as does the prohibition on the slaughter of non-ambulatory disabled cattle. However, as discussed earlier in this document, the OIE standards for trade in bovine-derived products, including meat and meat products, take into consideration the BSE risk status of a country or zone.

Therefore, FSIS is evaluating whether the Agency should consider a country's BSE risk when determining whether a country has implemented equivalent sanitary measures to those required by the United States to prevent human exposure to the BSE agent. Issues under consideration by FSIS include whether the Agency should develop and apply its own standards for determining a country's BSE risk; whether it should adopt and apply existing standards; and whether FSIS should conduct its own evaluation to determine a country's BSE risk for purposes of determining equivalence or whether it should rely on a third party evaluation.

Therefore, FSIS requests comments on the following questions:

34. Should FSIS provide an exemption for "BSE free" countries or countries with some other low-risk BSE designation?

35. If FSIS were to exempt "BSE free" countries from the provisions of the SRM rule, what standards should the Agency apply to determine a country's BSE status?

36. How would FSIS determine that country meets such standards? For example, should it rely on third party evaluations, such as the OIE, or conduct its own evaluation?

In the interim final rule on prohibited cattle material in human food and cosmetics published in the Rules and Regulations section of this **Federal Register**, FDA also has requested comments on standards to apply when determining another country's BSE status, providing an exemption for "BSE-free" countries, and how to determine that countries meet any standards that might be developed. FDA will work with USDA in developing a harmonized U.S. position for dealing with these issues.

VII. Submission of Public Comments

APHIS, FSIS, and FDA invite public comment on the issues and questions presented in this ANPRM. To facilitate each agency's review of comments, we ask that comments be submitted to the agency (APHIS, FSIS or FDA) that is seeking comment on the particular question the comment addresses. The agency or agencies that wish to receive comments on a particular issue are identified before each question or set of questions in sections V or VI. Comments should be submitted to all agencies only when comments address general questions or issues applicable to all agencies. Comment submissions should include the appropriate agency docket number(s). Please refer to the docket numbers and instructions for submitting comments in the **ADDRESSES** section at the beginning of this document.

Please also note that the comment periods established by each agency are different. FDA intends to issue a proposed rule on animal feeds subsequent to publication of this ANPRM. To facilitate FDA's consideration of those comments in developing the proposed rule, please submit comments specific to the FDA issues and questions to FDA prior to close of the 30-day comment period listed for FDA in the **DATES** section of this document. APHIS and FSIS will accept comments for 60 days, as provided in the **DATES** section of this document.

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 321, 342, 343, 348, 371, and 601–695.

Done in Washington, DC, this 8th day of July, 2004.

Bill Hawks,

Under Secretary, Marketing and Regulatory Programs, USDA.

Elsa Murano,

Under Secretary, Food Safety, USDA.

Dated: Done in Washington, DC, this 8th day of July, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

[FR Doc. 04–15882 Filed 7–9–04; 11:00 am]

BILLING CODE 3410–34–P; 3410–DM–P; 4160–01–P

country pursuant to a bilateral or multilateral agreement, only with respect to aliens whom DHS has chosen to place in removal proceedings under section 240 of the Act, as provided in 8 CFR 1240.11(g). For DHS regulations relating to determinations by asylum officers on this subject, see 8 CFR 208.30(e)(6).

* * * * *

5. Section 1208.30 is amended by:

a. Revising paragraphs (a) and (e); and by

b. Removing and reserving paragraphs (c), (d), (f) and (g)(1).

The revisions read as follows:

§ 1208.30 Credible fear determinations involving stowaways and applicants for admission found inadmissible pursuant to section 212(a)(6)(C) or 212(a)(7) of the Act.

(a) Jurisdiction. The provisions of this subpart apply to aliens subject to sections 235(a)(2) and 235(b)(1) of the Act. Pursuant to section 235(b)(1)(B), asylum officers have exclusive jurisdiction to make credible fear determinations, and the immigration judges have exclusive jurisdiction to review such determinations.

* * * * *

(e) Determination. For the standards and procedures for asylum officers in conducting credible fear interviews and in making positive and negative credible fear determinations, see 8 CFR 208.30(b), (c), (d), (e), (f), and (g)(1). The immigration judges will review such determinations as provided in paragraph (g)(2) of this section and 8 CFR 1003.42.

* * * * *

PART 1212—DOCUMENTARY REQUIREMENTS; NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

6. The authority citation for part 1212 is revised to read as follows:

Authority: 8 U.S.C. 1101 and note, 1103.

7. Section 1212.5 is revised to read as follows:

§ 1212.5 Parole of aliens into the United States.

Procedures and standards for the granting of parole by the Department of Homeland Security can be found at 8 CFR 212.5.

PART 1240—PROCEEDINGS TO DETERMINE REMOVABILITY OF ALIENS IN THE UNITED STATES

8. The authority citation for part 1240 is revised to read as follows:

Authority: 8 U.S.C. 1103, 1182, 1186a, 1224, 1225, 1226, 1227, 1251, 1252 note, 1252a, 1252b, 1362; secs. 202 and 203, Pub. L. 105–100, 111 Stat. 2160, 2193; sec. 902, Pub. L. 105–277, 112 Stat. 2681; sec. 1101, Pub. L. 107–269, 116 Stat. 2135.

9. Section 1240.11 is amended by adding a new paragraph (g), to read as follows:

§ 1240.11 Ancillary matters, applications.

* * * * *

(g) Safe third country agreement. (1) The immigration judge has authority to apply section 208(a)(2)(A) of the Act, relating to a determination that an alien may be removed to a safe third country pursuant to a bilateral or multilateral agreement, in the case of an alien who is subject to the terms of the agreement and is placed in proceedings pursuant to section 240 of the Act without being processed under section 235 of the Act. In an appropriate case, the immigration judge shall determine whether under the Agreement the alien should be returned to the safe third country, or whether the alien should be permitted to pursue asylum or other protection claims in the United States.

(2) An alien described in paragraph (g)(1) of this section is ineligible to apply for asylum, pursuant to section 208(a)(2)(A) of the Act, unless the immigration judge determines, by preponderance of the evidence, that:

(i) The agreement does not apply to the alien or does not preclude the alien from applying for asylum in the United States; or

(ii) The alien qualifies for an exception to the agreement as set forth in paragraph (g)(3) of this section.

(3) The immigration judge shall apply the applicable regulations in deciding whether the alien qualifies for any exception under the agreement that would permit the United States to exercise authority over the alien's asylum claim. The exceptions under the agreement are codified at 8 CFR 208.30(e)(6)(iii). The immigration judge shall not review, consider, or decide any issues pertaining to any discretionary determination on whether the alien should be permitted to pursue an asylum claim in the United States notwithstanding the general terms of the agreement, as such discretionary public interest determinations are reserved to the Department of Homeland Security. However, an alien in removal proceedings who is otherwise ineligible to apply for asylum under the agreement may apply for asylum if the Department of Homeland Security files a written notice in the proceedings before the immigration judge that it has decided in the public interest to allow the alien to pursue claims for asylum or withholding of removal in the United States.

(4) An alien who is found to be ineligible to apply for asylum under section 208(a)(2)(A) of the Act is ineligible to apply for withholding of removal pursuant to section 241(b)(3) of the Act and the Convention against Torture. However, the alien may apply for any other relief from removal for which the alien may be eligible. If an alien who is subject to section 208(a)(2)(A) of the Act is ordered removed, the alien shall be ordered removed to the safe third country in which the alien will be able to pursue his or her claims for asylum or protection under the laws of that country.

Dated: March 1, 2004.

John Ashcroft,

Attorney General.

[FR Doc. 04–5065 Filed 3–5–04; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 95

[Docket No. 03–080–2]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would amend the regulations regarding the importation of animals and animal products to recognize, and add Canada to, a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy into the United States via live ruminants and ruminant products. The proposed rule also set out conditions under which we would allow the importation of certain live ruminants and ruminant products and byproducts from such regions. This action will allow interested persons additional time to prepare and submit comments.

DATES: We will consider all comments that we receive on or before April 7, 2004.

ADDRESSES: You may submit comments by any of the following methods:

• Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 03–0801, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–080–1.

• E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 03–080–1" on the subject line.

• Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS Web site.

• Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

On November 4, 2003, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** (68 FR 62386–62405, Docket No. 03–080–1) a proposal to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and proposed to add Canada to this category. We also proposed to allow the importation of certain live ruminants and ruminant products and byproducts from such regions under certain conditions. Comments on the proposed rule were required to be received on or before January 5, 2004. In addition to inviting comments on the proposed rule itself, APHIS invited comments on an analysis the Agency had conducted of the risk of importing the animals and animal products in question from Canada under the conditions of the proposed rule. At the time the proposed rule was published, BSE had never been detected in the United States and only a single case had been reported in Canada (in Alberta in May 2003).

On December 23, 2003, the U.S. Department of Agriculture (USDA) announced a presumptive positive case of BSE in a Holstein cow in Washington State. The diagnosis was verified on December 25, 2003, by an international reference laboratory. The investigation that was conducted following detection of the disease revealed the animal was born in Canada and had most likely been exposed to the BSE agent in that country.

Since the date of detection of BSE in the cow in Washington State, the USDA and other Federal and State agencies have worked together closely to perform an epidemiological investigation, trace any potentially infected cattle, trace potentially contaminated rendered product, increase BSE surveillance, and take additional measures to address human and animal health. Additionally, an international panel of scientific experts appointed by the Secretary of Agriculture has provided a review of U.S. BSE response actions and has made recommendations for enhancements of the national BSE response program in the United States.[1]

Detection of BSE in the imported cow in Washington State occurred after APHIS conducted its analysis of the risk of importing ruminants and ruminant products and byproducts from Canada under the conditions of the proposed rule. Therefore, it is important for us to explain the extent to which we believe that detection may affect the conclusions of the risk analysis, and, consequently, the validity of the proposed rule. Therefore, we have prepared an explanatory document, discussed below, that addresses the effect of the detection of the imported cow on the analysis of risk that we conducted for the November 2003 proposed rule.

Effect of the Detection of BSE on APHIS's Analysis of Risk

The epidemiological investigation that was conducted following detection of BSE in an imported cow in Washington State[2] revealed several points that are relevant to whether and how that detection affects our analysis of the risk of importing ruminants and ruminant products from Canada under the conditions of the November 2003 proposed rule.

• The infected heifer was approximately 6 years and 8 months old at the time the disease was diagnosed. Its age indicated that it was born before implementation of a ban in Canada on feeding mammalian protein to ruminants and was most likely to have become infected before that feed ban was implemented.

• The animal was imported into the United States in 2001 at approximately 4 years of age.

Among the conditions for importing cattle from Canada under the proposed rule was the requirement that the animals be no more than 30 months old. This restriction was based on research indicating the most likely cattle to have infectious levels of the BSE agent are those older than 30 months. Additionally, the proposed rule required that the animals not have been fed ruminant protein.

Although the BSE-infected cow identified in Washington State was more than 30 months of age when it was diagnosed, it was obviously not imported under the conditions of the yet-to-be-implemented proposed rule, and would not have been allowed to be imported under the proposed rule. Further, as discussed in the risk analysis, a ban on feeding mammalian protein to ruminants was implemented in Canada in 1997 and compliance with that feed ban appears to have been, and to continue to be, good. The cow identified with BSE in the United States was born in Canada before the feed ban was implemented. Therefore, we continue to believe that the import controls of the proposed rule would be effective.

The analysis of risk we conducted addressed the issue of the prevalence of BSE in Canada. The risk analysis

[1] You may view the international panel's report on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html*. At the BSE page, click on the listing for "The Secretary's Foreign Animal and Poultry Disease Advisory Committee's Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States."

[2] A summary of the epidemiological investigation is included in our explanatory note document. Instructions for accessing the explanatory note document are included in this notice under the heading "How to View APHIS Risk Documents Related to this Notice."

presented evidence that the prevalence was very low and that Canada had strong BSE controls in place. Although the detection of an imported BSE-infected cow in Washington State means an additional animal of Canadian origin has been diagnosed with BSE since completion of the risk analysis and publication of the proposed rule, the total number of diagnosed cases attributed to that country remains low. Further, Canada has implemented strong measures to prevent the establishment, propagation, and spread of BSE among cattle in that country, to detect infected animals through surveillance, and to protect the Canadian animal and human food supplies.

Given the conditions APHIS is proposing for the importation of ruminants and ruminant products from Canada, we believe it is highly unlikely that BSE would be introduced from Canada under the proposed rule. Based on the factors discussed in the original risk analysis, along with risk mitigation measures currently in place and those that would be added by the proposed rule, we have concluded that a BSE case in a second cow of Canadian origin does not alter our risk estimate.

Canadian Investigation Following Detection of a BSE-Infected Cow in Washington State

The Canadian Food Inspection Agency (CFIA) initiated an epidemiological investigation specifically in response to the confirmation of a BSE-infected cow of Canadian origin in Washington State. This investigation was conducted concurrently and cooperatively with the U.S. investigation of animals from the same Canadian herd of origin. CFIA is continuing its epidemiological investigation.

The Government of Canada has also announced plans to enhance existing measures being taken in that country regarding BSE surveillance and animal tracking by increasing the number of animals tested for BSE annually and by strengthening Canada's animal identification program.[3]

Actions Taken in the United States After Detection of the Imported BSE-Infected Cow

Although the detection of an imported BSE-infected cow does not, in our view, alter the conclusions of our original risk analysis, it did raise consciousness of BSE challenges that might exist for the United States. As noted above, the United States is redirecting resources toward planning, implementation, and enforcement of measures to enhance BSE surveillance and to protect human and animal health.

Both the USDA and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) have either put in place or have announced additional safety measures in response to the detection of the case of BSE.[4] USDA requested a review of the U.S. BSE program by an international scientific panel and has received its recommendations. Although the U.S. Government has already taken significant actions that directly address many of the expert panel's recommendations, and is considering policy options to further address the recommendations, we believe the recent detection and investigation of the BSE case in a cow of Canadian origin demonstrate the effective nature of the surveillance and response measures currently in place.

The risk analysis we conducted for our November 2003 proposal was developed after, and took into consideration, the diagnosis of BSE in a cow in Canada in May 2003. In that analysis, we considered the sum total of the control mechanisms (*e.g.*, effectiveness of surveillance, import controls, and feed ban) in place in Canada at the time of the diagnosis and the actions taken by Canada following that diagnosis. The conclusion of our analysis was that those control mechanisms and actions were adequate to mitigate the risk of BSE being brought into the United States from Canada through the importation of ruminants and ruminant products, provided the conditions of the proposed rule were met. Enhancements the United States has made to its own BSE control program since the December 2003 detection—such as elimination of nonambulatory disabled cattle from the food chain, the removal of "specified risk materials" from human food, and increased surveillance—and the adoption of equivalent measures by Canada, continue to support our basic conclusions that ruminants and ruminant products can be safely imported.

Requirements of the November 2003 Proposed Rule in Light of Recent U.S. Measures

As noted above, the USDA has responded to the detection of the case of BSE in an imported BSE-infected cow with significant BSE risk mitigation measures in this country. Perhaps most importantly, parts of slaughtered animals that are considered at particular risk of containing the BSE agent in an infected animal (referred to as "specified risk materials" or "SRM's") have been banned from the human food supply. The USDA's Food Safety and Inspection Service (FSIS) has established as SRM's the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle over 30 months of age, as well as the tonsils and small intestine of cattle of all ages, and prohibits such SRM's from the human food supply. In addition, FSIS has, among other measures, required that nonambulatory, disabled cattle be excluded from the food supply. The Canadian Government has established similar safeguards in Canada.

The measures taken by FSIS do not restrict the slaughter of cattle in the United States based on the age of the animals—*i.e.*, meat from cattle 30 months of age or older will continue to be allowed into the human food supply. However, measures are in place to ensure that SRM's from such cattle do not enter the food supply. We now believe it would not be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided equivalent measures are in place to ensure that SRM's are removed when the animals are slaughtered, and that such other measures as are necessary are in place. We believe such measures are already being taken in Canada. We invite comment from the public regarding this change to the provisions we proposed in November 2003 regarding the importation of beef.

With regard to the importation of live animals from BSE minimal-risk regions, APHIS is currently evaluating the appropriate approach regarding such animals and intends to address that issue in a supplemental rulemaking proposal in the **Federal Register**.

Extension of Comment Period

In order to give interested persons an opportunity to comment on our November 2003 proposed rule in light of recent developments described above, we are reopening the comment period on Docket No. 03–080–1 for an additional 30 days. We will also

[3] These measures are discussed in greater detail in our explanatory note to the risk analysis we conducted for our November 2003 proposed rule, and may also be viewed on the Internet by accessing the CFIA Web site at *http:\\www.inspection.gc.ca*.

[4] A listing of each of the measures taken or announced is included in our explanatory note document. Instructions for accessing the explanatory note document are included in this notice under the heading "How to View APHIS Risk Documents Related to this Notice."

consider all comments received between January 6, 2004 (the day after the close of the original comment period), and the date of this notice.

How To View APHIS Risk Documents Related to This Notice

You may view the original analysis we conducted for our November 2003 proposed rule and the explanatory note to that analysis in our reading room (information on the location and hours of the reading room is provided under the heading **ADDRESSES** at the beginning of this proposed rule). You may also request a copy of each document by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the analysis and the explanatory note when requesting copies. You may also view the analysis and the explanatory note[5] on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov*. At the APHIS website, click on the "Hot Issues" button. On the next screen, click on the listing for "Bovine Spongiform Encephalopathy (BSE)." On the next screen, click on the listing for "BSE Canada." On the next screen, click on the listing for either "Risk Analysis" or "Explanatory Note: Risk Analysis."

Authority: 7 U.S.C. 450, 1622, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 4th day of March, 2004.

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–5265 Filed 3–5–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–198–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–9–10, –20, –30, –40, and –50 Series Airplanes; Model DC–9–81 (MD–81), –82 (MD–82), –83 (MD–83), and –87 (MD–87) Airplanes; and Model MD–88 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model DC–9–10, –20, –30, –40, and –50 series airplanes; Model DC–9–81 (MD–81), –82 (MD–82), –83 (MD–83), and –87 (MD–87) airplanes; and Model MD–88 airplanes. This proposal would require repetitive inspections and functional tests of the static port heater assemblies, an inspection of the static port heaters and insulators, and corrective actions if necessary. This action is necessary to prevent an electrical short of the static port heater from sparking and igniting the insulation blanket adjacent to the static port heater, which could result in smoke and/or fire in the cabin area. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by April 22, 2004.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2003–NM–198–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain "Docket No. 2003–NM–198–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.

FOR FURTHER INFORMATION CONTACT: Elvin Wheeler, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5344; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2003–NM–198–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2003–NM–198–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

As part of its practice of re-examining all aspects of the service experience of a particular aircraft whenever an accident occurs, the FAA has received the results of studies, done by Boeing, on the wiring of the static port heaters found on McDonnell Douglas Model

[5] The analysis is titled "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States." The explanatory note is titled "Explanatory Note-Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States."

Federal Register

Monday,
January 12, 2004

Part V

Department of Agriculture

Food Safety and Inspection Service

9 CFR Part 301, 309, et al.
Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter; Bovine Spongiform Encephalopathy Surveillance Program; Interim Final Rules and Notice

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 309, 310, 311, 318, and 319

[Docket No. 03–025IF]

Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to designate the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle, as "specified risk materials" (SRMs). The Agency is declaring that SRMs are inedible and prohibiting their use for human food. In addition, FSIS is requiring that all non-ambulatory disabled cattle presented for slaughter be condemned. The Agency is requiring that federally-inspected establishments that slaughter cattle and federally-inspected establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Establishments must incorporate these procedures into their HACCP plans or in their Sanitation SOPs or other prerequisite program. FSIS is taking this action in response to the diagnosis on December 23, 2003, by the U.S. Department of Agriculture of a positive case of bovine spongiform encephalopathy (BSE) in an adult Holstein cow in the State of Washington. This action will minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease. Infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with BSE at any stage of the disease.

DATES: This interim final rule is effective January 12, 2004. Comments on this interim final rule must be received by April 12, 2004.

ADDRESSES: Submit written comments to: FSIS Docket Clerk, Docket #03–025IF, Room 102, Cotton Annex, 300 12th and C Street, SW., Washington, DC 20250–3700. Reference materials cited in this document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday. Reference materials that are not copyrighted will also be available on the FSIS Web site at *http://www.fsis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Executive Associate, Policy Analysis and Formulation, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202)205–0495.

SUPPLEMENTARY INFORMATION:

Background

Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), FSIS issues regulations governing the production of meat and meat food products prepared for distribution in commerce. The regulations, along with FSIS inspection programs, are designed to ensure that meat and meat food products are safe, wholesome, unadulterated, and properly marked, labeled, and packaged. The FMIA prohibits anyone from selling, transporting, offering for sale or transportation, or receiving for transportation in commerce, any adulterated or misbranded meat or meat food product (21 U.S.C. 610).

Under the FMIA, a meat food product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m)(1)) or if it is for any reason unsound, unhealthful, unwholesome, or unfit for human food (21 U.S.C. 601(m)(3)). The FMIA requires that FSIS inspect the carcasses, parts of carcasses, and meat food products of all cattle, sheep, swine, goats, horses, mules, or other equines that are capable for use as human food to ensure that such articles are not adulterated (21 U.S.C. 604, 606). If the carcasses, parts of carcasses, and meat food products are found, upon inspection, to be not adulterated, FSIS marks them as "Inspected and passed" (21 U.S.C. 604, 606, 607). The FMIA gives FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the provisions of the Act (21 U.S.C. 621).

As discussed in greater detail below, infectivity has been confirmed in the brain, trigeminal ganglia, tonsils, spinal cord, DRG, and distal ileum of the small intestine of cattle experimentally infected with BSE, and in the brain, spinal cord, and eyes of cattle infected with BSE under field conditions. Data on the age distribution of clinical cases of BSE in the field reported in the United Kingdom indicate that clinical BSE disease has rarely been reported in cattle younger than 30 months of age.

In cattle experimentally infected with BSE, infectivity has been confirmed in the distal ileum at various stages of the disease process and as early as 6 months after oral exposure to the BSE agent. The tonsils of experimentally infected cattle have demonstrated apparently weak infectivity as early as 10 months after oral exposure to the BSE agent. The other tissues in which BSE infectivity has been confirmed have demonstrated infectivity at the end stages of disease, which, in experimentally infected cattle, was 32 months after exposure to the BSE agent and later. The brain, trigeminal ganglia, tonsils, DRG, and distal ileum are materials of experimentally infected cattle in which infectivity has been confirmed before the onset of clinical disease.

Based on these findings, FSIS has concluded that the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle are unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C 601(m)(3)). Therefore, FSIS is designating these materials as SRMs, declaring that they are inedible and, pursuant to its authority to promulgate regulations necessary to carry out the provisions of the FMIA, prohibiting their use for human food.

Because there are currently no restrictions on the incorporation of spinal cord and DRG into MS(Beef) meat food product, such product may contain concentrated amounts of these high-risk tissues. Therefore FSIS has concluded that, like the SRMs described above, MS(Beef) is unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)).

As discussed in detail below, surveillance data from European countries in which BSE has been detected indicate that non-ambulatory cattle are among the animals that have a greater incidence of BSE than other cattle. Surveillance data also indicate that clinical signs of BSE cannot always be observed in non-ambulatory cattle. Furthermore, due to limitations in the testing methods for BSE that are available today, certain tissues of cattle

infected with BSE may contain BSE infectivity even though the diagnostic test does not indicate that the animal has the disease. For the reasons presented above, FSIS believes that non-ambulatory disabled cattle present a risk of introducing the BSE agent into the human food supply. Therefore, FSIS has determined that the carcasses of non-ambulatory disabled cattle are unfit for human food under section 1(m)(3) of the FMIA and that all non-ambulatory disabled cattle that are presented for slaughter should be condemned.

By declaring SRMs and MS(Beef) inedible and prohibiting their use for human food, and by condemning all non-ambulatory disabled cattle, FSIS will ensure that materials that could present a significant risk to human health, but whose infectivity status cannot be readily ascertained, are excluded from the human food supply.

Because BSE was recently confirmed in a cow in the United States, FSIS has determined that the SRMs identified in this document are unfit for human food. Thus, the status of most of these materials has changed from edible to inedible. Such a change is likely to affect the underlying hazard analysis that must be conducted as prescribed by 9 CFR 417.4(a)(3). Therefore, in response to this change, FSIS expects that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle will reassess their HACCP plans in accordance with 9 CFR 417.4(a)(3) to address SRMs.

BSE and Variant Creutzfeldt-Jakob Disease

BSE is a progressive degenerative disease that affects the central nervous system (CNS) of adult cattle. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs), which include, among other diseases, scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Cruetzfeldt-Jakob disease (CJD) in humans. The typical incubation period (the time from when an animal becomes infected until it first shows disease signs) for BSE is believed to be from two to eight years. BSE was first documented in the United Kingdom in 1986 and has since been identified in approximately 21 other countries in Europe. BSE has also been confirmed in some non-European countries, including Japan, Israel, and Canada.

On December 23, 2003, USDA announced a presumptive diagnosis of BSE in an adult Holstein cow from Washington State. Samples were taken from the cow on December 9 as part of USDA's BSE surveillance program. The BSE diagnosis was made on December 22 and 23 by histopathology and immunohistochemical testing at the National Veterinary Services Laboratory, Ames, Iowa. On December 25, 2003, the International Reference Laboratory in Weybridge, England confirmed the diagnosis of BSE.

The agent that causes BSE and other TSEs has yet to be fully characterized. The theory that is most accepted in the scientific community is that the agent is a prion, which is an abnormal form of a normal protein known as cellular prion protein, although other types of agents have also been implicated. The agent is highly resistant to heat, ultraviolet light, ionizing radiation, and common disinfectants that normally inactivate viruses or bacteria.

In 1996, a newly recognized form of the human disease CJD, referred to as vCJD, was reported in the United Kingdom. Scientific and epidemiological studies have linked vCJD to exposure to BSE, probably through human consumption of beef products contaminated with the agent that causes BSE (Ref. 1–5 available for viewing by the public in the FSIS Docket Room). To date, approximately 150 probable and confirmed cases of vCJD have been reported worldwide.

The Centers for Disease Control and Prevention (CDC) leads a surveillance system for vCJD in the United States, and as of December, 2003, the disease has never been detected in residents of the United States that have never lived in or traveled to the United Kingdom for extended periods of time. In 2002, a probable case of vCJD was reported in a Florida resident who lived in the United Kingdom during the BSE epidemic. Epidemiological data indicate that the patient was likely exposed to the BSE agent before moving to the United States. (Ref. 6 available for viewing by the public in the FSIS Docket Room).

The United States government has implemented a number of measures to prevent BSE from entering the United States and to prevent the spread of the disease should it be introduced into the United States. Since 1989, USDA's Animal and Plant Health Inspection Service (APHIS) has prohibited the importation of live cattle and certain cattle products, including rendered protein products, from countries where BSE is known to exist. In 1997, due to concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, these importation restrictions were extended to include all of the countries in Europe. In 1997, FDA prohibited the use of most mammalian protein in the manufacture of animal feeds given to cattle and other ruminants. In December 2000, APHIS prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries because of concern that feed intended for cattle may have been cross-contaminated with the BSE agent. In addition, APHIS leads an ongoing, comprehensive, interagency surveillance system for BSE in the United States and, in cooperation with FSIS, has drafted an emergency response plan to be used in the event that BSE is identified in the United States. This plan was activated when the BSE test for the cow in Washington State came back presumptive positive on December 23, 2003. Other Federal agencies also have contingency plans that work in concert with the USDA plan.

BSE Infectivity

Animal age. The distribution and amount of the BSE agent in cattle infected with BSE is not known with certainty. It is generally accepted that in animals with clinical BSE disease, the brain and spinal cord contain the greatest concentration of the BSE agent, and that the quantity of the agent increases as the animals progress through the incubation period to the development of clinical disease. Thus, the total infective load in cattle in the early stages of the incubation period is believed to be much lower than in cattle approaching the end of the incubation period or in those cattle with overt clinical BSE. As stated above, the typical incubation period for BSE is believed to be between two to eight years.

Information on the age at which cattle develop clinical BSE under field conditions, *i.e.*, commercially reared cattle not part of a specially designed experiment, can be useful in identifying those cattle that, if infected with the BSE agent, are most likely to contain the highest levels of infectivity. Age-of-onset was known and recorded for approximately 135,000 cattle with confirmed clinical BSE in the United Kingdom between 1988 and August 2003 (Ref. 7, available for viewing by the public in the FSIS Docket Room). These data demonstrate that the age at which cattle develop clinical disease varies. The data from the United Kingdom show a gradual increase in the number of clinical BSE cases with increasing age, and that the number of confirmed cases peaks at 5 years of age. The lower ranges of this age distribution include some cattle younger than 30 months of age.

The age distribution data show that, of the cattle that developed clinical BSE in the field, only 0.01% were less than 30 months of age. Thus, cattle younger than 30 months of age are less likely to be in the later stages of BSE incubation than older BSE-infected cattle, and hence, are less likely to contain high levels of BSE infectivity. Research demonstrates that the incubation period for BSE appears to be linked to the infectious dose of the BSE agent received, *i.e.*, the larger the infectious dose received the shorter the incubation period (Ref. 8, available for viewing by the public in the FSIS docket room). Thus, given these observations, scientists that have studied the disease believe that the occurrence of BSE in young cattle is most likely the result of exposure to a very large dose of the BSE agent at a very young age.

Detection of BSE in cattle younger than 30 months of age. In October 2003, Japan reported a BSE case in a 23-month old bull, the 8th BSE case confirmed in that country. Earlier cases confirmed in Japan were in cattle over 5 years of age. This recent case apparently did not have clinical signs of disease and was detected as part of Japan's regular surveillance for BSE in which all cattle slaughtered for human consumption are screened for the disease. In reporting on this BSE case, Japanese officials stated that tests suggested that the form of the BSE agent found in the affected animal was atypical, and that they planned to conduct further studies on this form of the disease. A similar form of the atypical agent detected in the Japanese animal has been reported in two BSE cases in Italy. However the Italian animals were 11 and 12 years old. Japan has reported importing feed from Italy.

In early November 2003, shortly after reporting the confirmation of BSE in a 23-month-old animal, Japan reported that BSE was confirmed in a 21-month-old animal. The 21-month-old animal is Japan's 9th reported case of BSE. Like the 23-month-old animal, this animal apparently did not have clinical signs of disease. However, the abnormal prion protein detected in this animal does not appear to be the same as the apparently atypical form detected in the 23-month-old animal. Japanese officials reported that they will be conducting testing to determine if the tissues of these relatively young cattle that were recently found positive for BSE contain BSE infectivity.

The immediate implications of the recent detection of BSE in two animals younger than 24 months of age in Japan, one of which has an apparently atypical form of the disease, are not readily apparent at this time. Although rare, confirmed cases of BSE in animals younger than 30 months of age have also been reported in the United Kingdom and in some other European countries. As stated earlier in this document, a confirmed case of BSE in an animal less than 30 months of age generally implies that the animal was exposed to a large dose of the infective agent at a young age. From 1988 to 1996, during the height of the BSE epidemic in the United Kingdom when large amounts of infective agent were being circulated among cattle herds, 19 clinical cases of BSE were confirmed in cattle younger than 30 months of age (Ref. 9, available for viewing by the public in the FSIS docket room). The youngest confirmed case of BSE was in the United Kingdom in an animal with clinical disease at 20 months of age in 1992. However, as of September 30, 2003, no cases of BSE in cattle younger than 30 months of age have been detected in the United Kingdom since 1996, and only 3 cases have been found in European animals less than 30 months of age since 2001.

FSIS requests comment on the potential implications, if any, of the reported 21- and 23-month-old cases of BSE in Japan. The Agency is also requesting comments on whether, and if so how, it should modify the measures in this rulemaking to address the fact that, in rare instances, BSE has been confirmed in cattle younger than 30 months of age.

Infective tissues. Available data on the development and distribution of tissue infectivity in BSE-infected cattle are incomplete. Most of what is known comes from pathogenesis studies conducted in the United Kingdom (Ref. 10, 11, 12 available for viewing by the public in the FSIS Docket Room). In these studies, cattle were deliberately infected with BSE through oral exposure to the brains of cattle with confirmed BSE. The experimentally infected cattle were killed at regular intervals as the disease developed, and at each interval the tissues of the infected cattle were examined for histopathological changes consistent with BSE and for abnormal prion proteins. At each interval, tissues of the BSE infected cattle were also injected into mice to identify those tissues of cattle capable of transmitting the disease.

The pathogenesis studies involved a small number of cattle (30 animals) that received a large, uniform dose of the BSE agent at a very young age (4 months). Thus, the findings may not reflect the development and distribution of infectivity of cattle exposed to the BSE under field conditions, where the level and age of exposure to the BSE agent are unpredictable. Furthermore, the pathogenesis studies did not determine the rate at which the BSE agent increases in the tissues that have demonstrated infectivity or the tissues that the agent must pass through to reach its ultimate destination in the animal after it is ingested. However, the results of these studies are useful in that they provide experimental evidence of the distribution of the infective agent in BSE-infected cattle at various stages of the disease.

The pathogenesis studies demonstrate that in cattle infected with BSE, the total amount of infectivity in the animal, as well as the distribution of infectivity in the animal's body, change over time, with the highest levels of infectivity detected in the brain and spinal cord at the end stages of disease. In the studies, some cattle exhibited clinical signs of BSE as early as 35 months post oral exposure to the BSE agent. By 37 months post oral exposure, all of the 5 animals that were still alive demonstrated clinical evidence of BSE (animals had been serially sacrificed at set intervals). In cattle with clinical BSE, infectivity was demonstrated in the brain, spinal cord, DRG, trigeminal ganglia, and the distal ileum of the small intestine. (DRG are clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column. "DRG" as used in this document has the same meaning as the term "dorsal spinal nerve root ganglia." Trigeminal ganglia are clusters of nerve cells connected to the brain that lie close to the exterior of the skull.)

In one set of animals, infectivity was demonstrated in the bone marrow at 38 months post exposure, but these findings were not conclusive. At this time, bone marrow is not designated as SRM. However, in today's **Federal Register**, FSIS is announcing new requirements to limit the presence of bone marrow in meat produced from AMR systems, with iron as a marker. This action is not a food safety measure at this time but is related to misbranding.

In some cattle in the studies, BSE infectivity was demonstrated in the brain, spinal cord, and DRG as early as 32 months post oral exposure to the BSE agent. In addition, infectivity was demonstrated in these tissues three months before animals began to develop clinical signs of the disease. Infectivity was demonstrated in the distal ileum of cattle 6 to 18 months post oral exposure to the BSE agent and again at 38 months and 40 months post oral exposure.

A second phase of the pathogenesis studies that uses a cattle bioassay is being conducted to ensure that low levels of infectivity that may not have

been detected in the first phase using the mouse bioassay are not missed. The cattle bioassay, in which tissues from cattle deliberately infected with BSE are injected directly into the brains of BSE-free cattle, is considered to be several hundred-fold more sensitive in detecting BSE infectivity than the mouse bioassay. Preliminary results from the cattle bioassay demonstrate that, in addition to the materials that were found to contain infectivity when the mouse bioassay was used, the tonsils of calves 10 months post oral exposure to the BSE agent contain infectivity. However, because only one of five animals injected with infected tonsil material developed clinical BSE at 45 months post-inoculation, the level of infectivity in the tonsils appears to be very low. The second phase of the study is still underway and is not expected to be completed for several more years. (Ref. 8 and 13, available for viewing by the public in the FSIS Docket Room).

In cattle infected with BSE under field conditions, BSE infectivity has been confirmed in the brain, spinal cord, and retina of the eye at the end stages of the disease (Ref. 8 available for viewing by the public in the FSIS Docket Room).

BSE infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with the disease at any stage of the disease.

Proportion of infectivity in certain tissues. In 2001, the European Commission's Scientific Steering Committee (SSC), a scientific advisory committee for the European Union, considered the amount and distribution of BSE infectivity in a typical case of BSE and estimated that, in an animal with clinical disease, the brain contains 64.1% of the total infectivity in the animal and the spinal cord contains 25.6% of the total infectivity (Ref. 14 available for viewing by the public in the FSIS Docket Room). Thus, the brain and spinal cord of cattle with clinical BSE are estimated to contain nearly 90% of the total infectivity in the animal. According to the SSC, the remaining proportion of infectivity in a typical animal with clinical BSE is found in the DRG (3.8%), the trigeminal ganglia (2.6%), the distal ileum (3.3%), the spleen (0.3%), and the eyes (0.04%).[1] However, as mentioned above, in experimentally infected cattle BSE infectivity has been demonstrated in the distal ileum as early as 6 to 18 months post oral exposure to the BSE agent and in the tonsils as early as 10 months post exposure. Thus, in younger cattle infected with BSE, these materials apparently present the greatest risk of exposing humans to the BSE agent.

[1] For this study, low levels of infectivity were assumed for the spleen and eyes based on scrapie experiments. The spleen has not demonstrated infectivity in cattle.

Current Regulatory Requirements for Potentially Infective Materials

Under FSIS' regulations, most of the materials that have demonstrated BSE infectivity in cattle with clinical disease, *i.e.*, brain, eyes, trigeminal ganglia, spinal cord, DRG, and the distal ileum of the small intestine, may currently be used in some way for human food. The brains of all livestock species, including the brains of cattle, are permitted for human food, with the exception of brains from animals stunned by lead, sponge iron, or frangible bullets (9 CFR 310.18(b)). Unprocessed cattle brains are typically sold chilled, frozen, or canned, and are consumed as a variety meat. Cattle brains may also be used as a by-product ingredient in certain processed products. When used as a by-product ingredient, cattle brains must be listed in the ingredients statement on the labeling of the product and declared by species (9 CFR 317.2(f)(1)).

Cattle brains are also permitted to be used as a source material in edible rendering. Edible rendering involves the processing of materials inspected and passed for human food into products, such as edible oils, meals, beef extracts, beef protein, beef broths, beef stocks, and beef flavorings. Many of these products are regulated by FSIS and FDA.

Given the invariable presence of bone splinters, detached spinal cords from all livestock species, including cattle, are prohibited for use in the preparation of edible products (9 CFR 318.6(b)(4)). However, detached spinal cords may be used as a raw material in edible rendering (9 CFR 318.6(b)(4)). The labeling of extracts prepared from brains, spinal cords, or other organs or parts of the carcass other than fresh meat from all livestock species, including cattle, must include the true name of the parts from which the product was prepared, *e.g.*, "extract from beef brain" (9 CFR 317.8(b)(15)).

Vertebral columns from cattle contain both spinal cord and DRG. FSIS' regulations do not require that the spinal cord or DRG of cattle be removed from the vertebral column at the time of slaughter. Thus, some bone-in beef products may contain spinal cord, DRG, or both.

Bones from the vertebral column of cattle are permitted to be used as source materials in the production of processed products manufactured from edible rendering. When the vertebral columns from cattle are used in the production of such products, spinal cord and DRG that remain attached to the vertebral column could potentially become dislodged and incorporated into the final product. Under the FSIS regulations, the labeling of the final product is not required to disclose the fact that the product may contain spinal cord or DRG.

Bones from the vertebral column of cattle are also permitted for use as a source material in meat recovery systems that use pressure to separate beef muscle tissue from bones. When the vertebral columns are used as a source material in these systems, spinal cord and DRG may become dislodged from the vertebral bones and incorporated into the final product. The use of vertebral columns in systems that mechanically separate meat and meat products from bone, and the labeling requirements for such products, are discussed in greater detail below.

Casings made from the small intestine, including the distal ileum, of cattle are permitted to be used as containers for meat food products (9 CFR 318.6(b)(1)). Cattle intestines, including the distal ileum, are also permitted for use as ingredients in meat food products that do not have an FSIS prescribed standard of identity, provided that the products are properly labeled (9 CFR 318.6(b)(8)).

FSIS' regulations do not prohibit the use of cattle eyes for human food, although direct consumption of such materials is uncommon in the United States. The tonsils of all livestock species, including cattle, are prohibited for use as ingredients of meat food products (9 CFR 318.6(b)(6)). The trigeminal ganglia of cattle are not sold directly as consumer products. However, the heads of cattle (commonly referred to as "market heads") are permitted for use as human food and are sold to retail establishments where they are used to produce edible products. Some retail establishments sell market heads of cattle directly to consumers. Cattle market heads contain skull, eyes, trigeminal ganglia, and fragments of brains.

Meat that has been trimmed from the head and cheeks of cattle is permitted to be used in FSIS-regulated products, although some product standards place certain restrictions on the use of head and cheek meat (for examples see 9 CFR 319.81, 9 CFR 319.199, 9 CFR 319.300 9 CFR 319.301, and 9 CFR.303) Head or cheek meat may contain CNS materials if the meat is not removed before the skull is fragmented or split. Although rare, the skulls of cattle are sometimes

intentionally split to remove materials contained within the cranial cavity, such as the pituitary gland. The skulls of cattle are sometimes unintentionally fragmented, and the brains of the animals exposed, when a mechanical device is used to remove horns from cattle. In some instances, in addition to the fragmentation that occurs during horn removal, the brain has also been penetrated by the captive bolt of a stun gun, which results in a hole with weeping material that may contain CNS tissue. In these cases, when the head and cheek meat are removed, the heads of the cattle may be manipulated in such a way as to potentially contaminate the meat. Contamination of head or cheek meat with trigeminal ganglia is unlikely because the trigeminal ganglia are embedded within the skull and are not likely to be removed when the meat is harvested.

Meat Produced Using Advanced Meat Recovery Systems and Mechanically Separated (Species) Meat Food Product

Advanced Meat Recovery. Advanced Meat Recovery (AMR) is a technology that enables processors to remove the attached skeletal muscle tissue from livestock bones without incorporating significant amounts of bone and bone products into the final meat product. When produced properly, product from AMR systems is comparable to meat derived by hand deboning and can be labeled as "meat" (9 CFR 301.2). Under the FSIS regulations, spinal cord is not a component of meat, and therefore, product from AMR systems identified as "meat" that contains spinal cord is misbranded.

From January through August 2002, FSIS conducted a survey of AMR products derived from the vertebral column of cattle to establish a baseline for the prevalence of spinal cord and DRG tissue in beef AMR products (referred to as the 2002 Beef AMR Survey) (Ref. 15 and 16, available for viewing by the public in the FSIS docket room and on the Internet at *http://www.fsis.usda.gov/oa/topics/AMRAnalysis.pdf and http://www.fsis.usda.gov/OA/topics/AMRSurvey.pdf).* In the 2002 Beef AMR Survey, the Agency found that while some establishments were able to consistently produce beef AMR product that was free of spinal cord and DRG tissue, a majority of the establishments had difficulty keeping spinal cord and DRG out of their AMR products. Overall, FSIS found that that approximately 76% (25 of 34) of the establishments whose AMR product was tested had positive laboratory results for spinal cord, DRG, or both in their final beef AMR products. The survey also found that approximately 35% (89 of 256) of all final AMR product samples that were tested had positive laboratory results for spinal cord, DRG, or both.

In March 2003, after completion of the 2002 Beef AMR Survey, FSIS implemented a routine regulatory sampling program of beef products from AMR systems as an additional measure to prevent misbranding of beef AMR products. Prior to the implementation of this regulatory sampling program, FSIS inspection program personnel collected AMR product samples for analysis for the presence of spinal cord tissue only if they believed that the establishment was not completely removing spinal cord from the vertebral column before the vertebral bones entered the AMR system (FSIS Directive 7160.2, April 14, 1997). Under the revised regulatory sampling program, FSIS inspection program personnel take samples of beef AMR product on a routine basis to verify that spinal cord tissue is not present in such product (FSIS Directive 7160.03, Revision 1, August 25, 2003). If spinal cord tissue is detected in beef AMR product, FSIS inspection program personnel take regulatory control action against the AMR product and equipment to prevent misbranded product from entering commerce. If the establishment has distributed misbranded beef AMR product, FSIS requests a voluntary recall.

Removal of the spinal cord before the vertebral columns enter the AMR system does not always ensure that spinal cord or DRG will not be incorporated into the final product. The Harvard study found that, if a beef carcass is mis-split when the spinal cord is removed, a portion of the spinal cord may remain encapsulated in the spinal canal of the vertebral column, and, if it is not removed before the vertebral bones enter the AMR system, the spinal cord could contaminate the final AMR product. Even when the spinal cord is completely removed from the vertebral column, the DRG of cattle are firmly attached to the bones of the vertebral column and are not removed along with the spinal cord. Thus, removing the spinal cord from the vertebral column does not prevent the DRG from entering an AMR system and becoming incorporated into the final AMR product.

Although FSIS and the regulated industry have recently taken actions to prevent the incorporation of spinal cord and, in some instances, DRG, in beef AMR products (Ref. 15 and 16, available for viewing by the public in the FSIS docket room), FSIS continues to detect spinal cord and DRG in its routine regulatory sampling of beef AMR products, although to a lesser extent than it did in the 2002 Beef AMR Survey. In its routine regulatory sampling conducted from March to December in 2003, FSIS detected spinal cord in 23 of 340 randomly scheduled samples, an estimated prevalence of 6.8 percent. In addition, the prevalence in follow-up samples was 13.6 percent, indicating that establishments with an initial positive continued to have some problems controlling for spinal cord in beef AMR systems. While FSIS was testing samples for spinal cord, FSIS also recorded the results for DRG. The prevalence for DRG was found in 10.9 percent of the samples in which DRG was recorded.

Under the current regulations, AMR product that contains DRG is not misbranded and can be identified as meat. However, given the nature of DRG, and the fact that BSE has been confirmed in a cow in the United States, FSIS has reconsidered its approach to this tissue and is issuing a separate interim final rule on AMR systems in this edition of the **Federal Register** that reflects recent developments that have occurred with regard to BSE. The interim final rule on AMR systems also establishes non-compliance criteria to discern "meat" from non-meat product.

Mechanically Separated (MS)(Beef). MS(Beef) meat food product is a finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses that meets the specifications contained in 9 CFR 319.5, the regulation that prescribes the standard of identity for MS(Species). Unlike AMR systems in which bone and bone products are not purposefully incorporated in the final meat product, MS(Species) systems are designed to purposefully incorporate significant amounts of bone and bone components in the resulting meat food product. The specifications for product identified as MS(Species) in 9 CFR 319.5 do not establish limits on the incorporation of spinal cord or DRG into this product. Although beef products produced using AMR systems that contain spinal cord cannot be identified as meat, if these products meet the specifications contained in 9 CFR 319.5, they are permitted to be labeled as MS(Beef).

Under the current regulations, MS(Species) product is permitted for use as an ingredient in other processed meat and poultry products in limited amounts (9 CFR 319.6). When MS(Beef) is used as an ingredient in meat or poultry products, it must be identified in the ingredients statement as

MS(Beef). However, the fact that MS(Beef) may contain spinal cord or DRG is not required to be conveyed on the labeling of MS(Beef) product or processed products that contain MS(Beef).

The fact that MS(beef) has been permitted to include spinal cord and DRG makes this product an obvious source of potential human exposure to the BSE agent. Given that a case of BSE was recently confirmed in the United States, FSIS believes that it is necessary to remove this high-risk product from the human food supply. Therefore, in this interim final rule, the Agency is banning the use of MS(beef) for human food. Accordingly, no product may bear the label (MS(Beef)). However, certain products from bones that do not contain CNS tissue, *e.g.*, long bones, that may contain excess bone solids or bone marrow may be produced but must be labeled with an appropriate common or usual name (refer to the interim final rule, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery Systems," docket number 03–038IF published in this edition of the **Federal Register**).

The Harvard Risk Assessment

In April 1998, USDA commissioned the Harvard Center for Risk Analysis to conduct an analysis and evaluation of the current measures implemented by the United States government to prevent the spread of BSE in the United States and to reduce the potential exposure of Americans to the BSE agent. The risk assessment (referred to below as the Harvard study) reviewed available scientific information related to BSE and other TSEs, assessed pathways by which BSE could potentially occur in the United States, and identified measures that could be taken to protect human and animal health in the United States (Ref. 17, available for viewing by the public in the FSIS docket room and on the Internet at *http://www.fsis.usda.gov/OA/topics/bse.htm).*

The Harvard study concluded that if introduced, due to the preventive measures currently in place in the United States, BSE is extremely unlikely to become established in the United States. Should BSE enter the United States, the Harvard study concluded that only a small amount of potentially infective tissues would likely reach the human food supply and be available for human consumption. The Harvard study expressed the amount of infectivity in terms of cattle oral ID50s for the purpose of quantifying both animal and human exposure to the BSE agent. A cattle oral ID50 is the amount of infectious tissue that would be expected to cause 50% of exposed cattle to develop BSE.

Because the exact quantitative relationship between human exposure to the BSE agent and the likelihood of human disease is unknown, the Harvard study did not evaluate the quantitative likelihood that humans will develop vCJD if BSE were introduced into the United States.

The Harvard study also did not address potential human exposure to the BSE agent through products containing ingredients of bovine origin, such as some pharmaceuticals, gelatin, and beef stocks, extracts, and flavorings. Many of these products are derived through the edible rendering process. FSIS is working with FDA, the agency that regulates the use of these products, to address the impact of this issue.

The Harvard study identified three pathways or practices that could contribute most to either human exposure to the BSE agent or to the spread of BSE should it be introduced into the United States. The three pathways are:

- Noncompliance with FDA regulations prohibiting the use of certain proteins in feed for cattle and other ruminants;
- Rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed;
- Inclusion of high-risk tissue from cattle, such as brain and spinal cord, in edible products.

FDA and USDA's APHIS are taking action to address the first two pathways. FDA is enhancing its enforcement of the feed ban and is evaluating whether further rulemaking is needed (*see* Advance Notice of Proposed Rulemaking, "*Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed*," 67 FR 67572, November 6, 2002). APHIS is developing approaches to control the potential risk that dead stock and non-ambulatory animals could serve as potential pathways for the spread of BSE (*see* Advance Notice of Proposed Rulemaking, "*Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species*," 68 FR 2703, January 21, 2003). FSIS is prohibiting the use of certain materials from cattle for human food to address the third potential pathway identified in the Harvard study, the inclusion of high-risk tissues in edible product. In addition, in a separate rulemaking published in this edition of the **Federal Register**, FSIS is prohibiting the use of penetrative stunning devices that inject air into the cranial cavity of cattle to ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughter process (*see* "*Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter*," Docket #01–033IF). Although FSIS is not aware of any cattle slaughter establishments in the United States that use air-injection stunning, research has shown that this practice poses a risk of exposing humans to materials that could contain the BSE agent. Given that a case of BSE was recently confirmed in the United States, FSIS believes that this prohibition is a necessary measure to help strengthen the U.S. Government's actions to prevent human exposure to the BSE agent.

The Harvard study concluded that, based on conditions as they existed in 2001, if 10 infected cows were introduced into the United States, on average, three additional new cases of BSE in cattle would be expected. In fact, Harvard predicted that there was a 75 to 95% chance that there would be no new cases at all. The extreme case (95th percentile of the distribution) predicted 11 new cases. However, in all cases, the system in 2001 was robust enough so that model predicts that the disease would be quickly cleared from the United States with virtually no chance that there would be any infected animals 20 years following the import of the 10 infected cattle.

The Harvard study concluded the greatest sources of potential human exposure to the BSE agent would be human consumption of cattle brain (26% of the total potential exposure on average), cattle spinal cord (5% of the total potential exposure on average), and beef products derived from AMR systems (57% of the total potential exposure on average). The Harvard study also determined that other potential human exposure routes to the BSE agent include consumption of bone-in beef (11% of the total potential exposure on average), and intestine (2% of the total potential exposure on average). However, as stated in the Harvard study report, these estimates are likely to overstate true human exposure because they represent the amount of infectivity presented for human consumption but do not take into account waste or actual consumption rate. For example, the reported quantity for potential exposure to infectivity in bone-in beef reflects the presence of spinal cord and DRG in a fraction of cuts like T-bone steaks, although the spinal cord and DRG may never be consumed in these cuts of meat.

The Harvard study divided potential sources of human exposure to BSE infectivity into two categories: specific high-risk tissues and contamination of low risk tissues with high-risk tissues. Specific high-risk tissues identified by Harvard, in order of infectivity, include: brain, spinal cord, DRG, distal ileum, and the trigeminal ganglia and other tissues found in the head (*e.g.*, eyes). Since brain and spinal cord of cattle infected with BSE contain most of the BSE infectivity in the animal, the Harvard study concluded that, if BSE were present in the United States, human consumption of bovine brains and spinal cords would be an obvious source of exposure to the BSE agent.

The Harvard study identified the production of meat through the use of AMR systems as the most important means by which low risk tissue can become contaminated with high-risk tissues because AMR systems can leave spinal cord and DRG in the recovered meat. Assuming that there is no SRM ban in place, the Harvard study estimated that beef AMR product could account for approximately 57% of the potential human exposure to the BSE agent.

Specified Risk Materials (SRMs)

Materials designated as SRMs. In determining which materials of cattle should be removed from the human food supply, FSIS considered the data on the age distribution of confirmed BSE cases in the United Kingdom, the findings of the pathogenesis studies conducted in the United Kingdom, and the findings of the BSE risk analysis conducted by Harvard.

After considering the factors mentioned above, together with the fact that a case of BSE was recently confirmed in the United States, FSIS has decided to designate the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle as SRMs, declare them inedible, and prohibit their use for human food. The Agency believes that removing these materials from the human food supply is a prudent and appropriate measure for preventing human exposure to the BSE agent in the United States.

Except for the skull and vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) of cattle 30 months of age and older, the materials listed as SRMs in this interim final rule are all materials that have demonstrated infectivity in cattle naturally or experimentally infected with BSE. Thus, in this rule, FSIS is designating all materials from cattle that have demonstrated BSE infectivity as SRMs, regardless of the level or proportion of infectivity contained in each tissue.

Although the skull or vertebral column of cattle infected with BSE have not demonstrated infectivity, the skull contains the eyes, trigeminal ganglia, and brain, and the vertebral column contains DRG and spinal cord. Thus, because they contain high-risk tissues, FSIS is including skulls and vertebral columns (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older in the list of SRMs that the Agency is declaring inedible and prohibiting for human food. Head meat, cheek meat, and tongue are not part of the skull. Therefore, under this interim final rule, these materials may continue to be used for human food, provided they are not contaminated with SRM. Unlike other parts of the vertebral column, the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum do not contain spinal cord or DRG. Therefore, FSIS is excluding these parts of the vertebral column from the materials designated as SRMs. Under this interim final rule, bone-in beef from cattle 30 months of age and older may be prepared from these sections of the vertebral column. These sections of the vertebral column may also be used as a source material for products produced from edible rendering.

The Harvard study identified the production of meat through the use of AMR systems as the most important means by which low risk tissue can become contaminated with high-risk tissues, such as spinal cord and DRG. Furthermore, as discussed above, although FSIS and the regulated industry have taken actions to prevent the incorporation of spinal cord and, in some instances, DRG, in beef AMR products, FSIS continues to detect spinal cord and DRG in its routine regulatory sampling of this product. By designating the vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older as SRM and prohibiting its use for human food, FSIS will ensure that spinal cord and DRG from cattle 30 months of age and older are not incorporated into beef AMR product.

The Harvard study determined that some potential exposure to BSE infectivity would result from the presence of spinal cord and DRG in certain bone-in cuts of beef, such as T-bone steaks. By designating vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older as SRM and prohibiting its use for human food FSIS will ensure that bone-in cuts of meat from cattle 30 months of age and older will not contain spinal cord or DRG.

The Harvard study did not address potential human exposure to the BSE agent through beef stocks, broths, or other products produced from the edible rendering process. However, it is possible that, when vertebral column bones are used as a source material for products produced from edible rendering, spinal cord and DRG could become dislodged from the vertebral bones and incorporated into the final product. By designating vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older as SRM and prohibiting its use for human food FSIS will ensure that spinal cord and DRG from cattle 30 months of age and older will not be incorporated into beef products produced from the edible rendering process.

Because of its proximity to the vertebral column, some hand-deboned meat may contain DRG depending on the technique used to recover the meat from the bone. Thus, hand-deboned meat from cattle could be a potential source of human exposure to DRG. FSIS is not aware of any data on the extent to which DRG are found in hand-deboned meat. FSIS is examining this issue in a study it is conducting to delineate the characteristics of hand-deboned meat. FSIS is not, at this time, prohibiting hand-deboned meat from the vertebral columns of cattle 30 months of age and older for use as human food. The Agency requests comments on this issue.

The SRMs prohibited for human food in this interim final rule are the same materials prohibited for use as human food by Canada, thus establishing a consistent standard in both countries. The Canadian SRMs include the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, and DRG from cattle 30 months of age and older, and distal ileum from all cattle. Although the vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar

vertebrae, and the wings of the sacrum) from cattle 30 months of age and older is not identified as SRM in the Canadian regulations, to ensure complete removal of potentially risky DRG from the human food supply, the Canadian Food Inspection Agency (CFIA) requires that the vertebral column of cattle 30 months of age and older, excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum, be removed and disposed of as inedible product (Meat Hygiene Directive 2003–18 (Amended), July 24 2003). The CFIA also prohibits the use of vertebral columns from cattle 30 months of age and older as a raw material in the preparation of mechanically separated meat or finely textured meat (Meat Hygiene Directive 2003–18 (Amended), July 24, 2003). The Canadian provisions for the removal of SRMs from the carcasses of cattle slaughtered in official Canadian establishments can be accessed on the Internet at *http://www.inspection.gc.ca/english/anima/meavia/mmopmmhv/chap4/annexne.shtml.*

The Canadian SRMs include the distal ileum from all cattle. However, the CFIA presently requires that the small intestine of all cattle be removed and disposed of as inedible product (Meat Hygiene Directive 2003–18 (Amended), July 24, 2003). Therefore, FSIS is designating, consistent with the Canadian rule, the distal ileum of the small intestine as SRM. To ensure that the distal ileum is completely removed from the carcass, FSIS is requiring that establishments remove the entire small intestine and that it be disposed of as inedible. Processors may be able to effectively remove just the distal ileum, and, accordingly, the Agency requests comments on this issue.

Rationale. Given the way that infectivity occurs in BSE-infected cattle, and the fact that a case of BSE has been detected in the United States, FSIS has determined that certain materials from cattle present sufficient risk of exposing humans to the BSE agent that it is prudent and appropriate to find that such materials are unfit for human food within the meaning of section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)). For the reasons presented above, FSIS has concluded that these materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle.

The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle, present a persistent risk of exposing humans to the BSE agent because, in pre-clinical BSE-infected cattle, infectivity in most of these tissues is not readily ascertainable. Thus, humans could unknowingly be exposed to the BSE agent through consumption of these materials.

By designating the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle as SRMs, declaring that they are inedible, and prohibiting their use for human food, FSIS will ensure that materials that could present a significant risk to human health, but whose infectivity status cannot be readily ascertained, are excluded from the human food supply.

Procedures for the Removal, Segregation, and Disposition of SRMs

In this interim final rule, FSIS is requiring that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs (section 310.22(d)(1)). The Agency is not prescribing specific procedures that establishments must follow because FSIS believes that establishments should have the flexibility to implement the most appropriate procedures that will best achieve the requirements of this rule.

Establishments are responsible for ensuring that SRMs are completely removed from the carcass, segregated from edible products, and disposed in an appropriate manner. Establishments must address their control procedures in their HACCP plans, Sanitation SOPs, or other prerequisite programs. FSIS will ensure the adequacy and effectiveness of the establishment's procedures.

This interim final rule also requires (section 310.22(d)(4)) that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle maintain daily records that document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and that the establishments make these records available to FSIS personnel on request.

FSIS will develop compliance guidelines for use by very small and small establishments to assist them in the development of validated methods for meeting the requirements of this interim final rule. FSIS believes that the use of the Canadian guidance on SRM removal generally is acceptable. FSIS will assess whether additional guidance is necessary (see the FSIS docket room and the FSIS Web site for the link to the Canadian and other compliance guidance information).

Verification of the Age of Cattle

Most of the materials that FSIS is prohibiting for use as human food in this rulemaking are from cattle 30 months of age and older. Thus, FSIS is prescribing the method that inspection program personnel will use to determine the age of cattle slaughtered in official establishments, to verify that the establishments are effectively segregating SRMs from edible materials.

The Agency is aware of two methods that can be used to verify the age of cattle slaughtered in official establishments: (1) Documentation that identifies the age of the animal, such as a birth certificate, cattle passport, or some other form of identification, that is presented with the animal when it arrives for slaughter, and (2) examination of the dentition of the animal to determine whether at least one of the second set of permanent incisors has erupted (the permanent incisors of cattle erupt from 24 through 30 months of age). The Agency has decided to use a combination of both methods.

If the establishment has records that document the age of the cattle slaughtered in the facility, FSIS inspection program personnel will examine the records. If the inspection program personnel conclude that the records are accurate and reliable, they will accept the records as verification of the age of the cattle. However, if FSIS inspection program personnel examine the records and find significant reasons for questioning their validity, they will verify the age of the cattle through dental examination. If the establishment does not have records that document the age of the cattle presented for slaughter, or the inspection program personnel have any reason to question the age of the animals, the Agency will verify age through dental examination.

In establishments that only process the carcasses and parts of carcasses of cattle, the Agency will verify age through establishment records that document the age of the cattle from

which the carcasses were derived. If the establishment does not have records that document the age of the cattle from which the carcasses were derived, it must handle all carcasses and parts of carcasses as if they came from cattle 30 months of age and older.

Although there are various methods of cattle identification in the United States, there is no national cattle identification system. Thus, there is currently no uniform standard of documentation that FSIS can rely on to accurately verify the age of cattle slaughtered in official establishments. On December 30, 2003, the Secretary of Agriculture announced that the USDA will implement a system of national animal identification. The development of such a system has been underway for more than a year and a half to achieve uniformity, consistency, and efficiency across this national system.

FSIS has developed instructions for use by its inspection personnel in verifying the age of cattle that is available for viewing by the public in the FSIS docket room and posted on the FSIS Web site.

Non-Ambulatory Disabled Cattle

Current regulatory requirements. FSIS' regulations prohibit for use as human food all livestock, including cattle, with clinical signs of a CNS disorder (9 CFR 309.4) and livestock that are in a dying condition or that died otherwise than by slaughter (9 CFR 309.3). Under the current regulation, all seriously crippled livestock and livestock commonly termed "downers" presented for slaughter are automatically suspected of being affected with a disease or condition that may require condemnation of the animal, in whole or in part, and are identified as "U.S. Suspects" (9 CFR 309.2(b)). Such animals are examined at ante-mortem inspection by an FSIS veterinarian, and a record of the veterinarian's clinical findings accompanies the carcass to post-mortem inspection if the animal is not condemned on ante-mortem inspection.

Post-mortem inspections of the carcasses of "U.S. Suspect" livestock are performed by veterinarians rather than by food inspectors, and the results of this inspection are recorded. "U.S. Suspects," unless otherwise released pursuant to 9 CFR 309.2(p), must be set apart and slaughtered separately (9 CFR 309.2(n)). If, on post-mortem inspection, the meat and meat food products from such animals are found to be not adulterated, such products may be used for human food (9 CFR 311.1).

Non-ambulatory cattle and BSE. Surveillance data from European countries in which BSE has been detected, indicate that cattle with clinical signs of a CNS disorder, dead cattle, and cattle that can not rise from a recumbent position (in Europe these cattle are distinguished either as "fallen stock" if not for human consumption or "emergency slaughter" cattle if for human consumption) have a greater incidence of BSE than healthy slaughter cattle. For example, in 2002 the EU reported that for healthy cattle 55–60 months of age, there were 0.55 positive tests for BSE per 10,000 animals tested compared with 3.05 positive tests for BSE per 10,000 cattle tested for the high-risk cattle (*i.e.*, fallen stock, emergency slaughter and animals that show clinical signs of BSE on ante-mortem inspection) (Ref. 18, available for viewing by the public in the FSIS docket room). In addition, an analysis of a targeted screening program for BSE in Switzerland found that when high-risk cattle were targeted for BSE testing, the odds of finding a BSE case was 49 times higher in fallen stock and 58 times higher in emergency-slaughtered cattle than in cattle tested under passive surveillance, *i.e.*, clinical BSE suspects reported to the veterinary authorities (Ref. 19, available for viewing by the public in the FSIS docket room). This study also found that the BSE cases detected through targeted screening of high risk animals were on average four months younger than the BSE cases detected through passive surveillance of clinical suspects.

Surveillance for BSE in Europe has also shown that the typical clinical signs associated with BSE cannot always be observed in non-ambulatory cattle infected with BSE because the signs of BSE often cannot be differentiated from the typical clinical signs of the many other diseases and conditions affecting non-ambulatory cattle. Furthermore, as discussed in greater detail below, there are limitations with the diagnostic tests for BSE that are available today. Under the current testing methods, which are conducted on sections of the brain or spinal cord, certain tissues of cattle infected with BSE, such as the distal ileum and tonsils, may contain BSE infectivity even though the diagnostic test does not show that the animal has the disease. Thus, permitting the carcasses of non-ambulatory cattle to be used for human food if the animal tests negative for BSE will not provide the same level of protection against human exposure to the BSE agent that prohibiting these cattle from entering the human food supply will.

Revised regulatory requirements. Because they present a risk of introducing the BSE agent into the human food supply, FSIS has determined that the carcasses of non-ambulatory disabled cattle are unfit for human food under section 1(m)(3) of the FMIA and that all non-ambulatory disabled cattle that are presented for slaughter should be condemned. Therefore, FSIS is amending its ante-mortem inspection regulations to require the condemnation of non-ambulatory disabled cattle presented for slaughter.

Specifically, FSIS is amending the regulations that prescribe requirements for "U.S. Suspect" livestock in 9 CFR 309.2 by replacing the reference to "animals commonly termed 'downers'" in § 309.2(b) with the term "non-ambulatory disabled livestock." FSIS is making this modification because there is currently no regulatory definition of "downer" and the Agency believes that the term "non-ambulatory disabled" more accurately describes the cattle that it believes should be prohibited for human food. "Non-ambulatory disabled livestock" is defined as livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions. Thus, this definition includes livestock that are non-ambulatory due to an acute injury in route to the slaughter facility, such as a broken leg, as well as livestock that are non-ambulatory due to an underlying pathological condition.

FSIS is excluding all non-ambulatory disabled cattle from the human food supply, regardless of the reason for their non-ambulatory status or the time at which they became non-ambulatory. Thus, if an animal becomes non-ambulatory in route to the establishment due to an acute injury, it must be humanely removed from the truck, humanely euthanized, and the carcass properly disposed of. Likewise, cattle that become non-ambulatory on the establishment premises, such as an animal that breaks its leg as it is unloaded from the truck, are also required to be humanely moved, humanely euthanized, and the carcass properly disposed of.

FSIS is also amending the regulations that prescribe requirements for dead, dying, disabled, or diseased and similar livestock in 9 CFR 309.3 to require that non-ambulatory disabled cattle be condemned and disposed of in accordance with 9 CFR 309.13. Unless another provision in part 309 applies, under § 309.13, condemned livestock must be killed by the establishment, if

not already dead. Such animals cannot be taken into the establishment to be slaughtered or dressed, or conveyed into any department of the establishment that is used for edible products. The carcasses of condemned livestock must be disposed of in the manner provided for in part 314.

Under part 314, condemned carcasses must be disposed of by "tanking," *i.e.*, inedible rendering (9 CFR 314.1). For those establishments that do not have facilities for tanking, condemned carcasses may be disposed of by incineration or denatured by crude carbolic acid, cresylic disinfectant, a formula consisting of one part FD&C No. 3 green coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or any other proprietary material approved by the Administrator of FSIS (9 CFR 314.3). The Agency is aware that many establishments use activated charcoal to denature inedible materials. Therefore, FSIS recognizes activated charcoal as a proprietary substance approved by the Administrator.

The regulations in 9 CFR 311.27 permit injured livestock to be slaughtered for humane reasons at hours when an inspector is not available to perform ante-mortem inspection, provided that the carcasses and parts of such animals are kept for inspection. To ensure that non-ambulatory disabled cattle are not slaughtered under this provision and their carcasses and parts used for human food, FSIS is amending 9 CFR 311.27 to prohibit the carcasses and parts of carcasses from cattle slaughtered on an emergency basis without ante-mortem inspection from being used for human food. Without performing ante-mortem inspection on cattle slaughtered on an emergency basis, FSIS inspection program personnel cannot determine whether the carcasses or parts from such cattle came from a non-ambulatory disabled animal, and thus cannot find that the carcasses and parts from these emergency slaughter cattle are not adulterated.

Testing Cattle for BSE

There is no sensitive and reliable live animal test for BSE, and the available post-mortem diagnostic tests can only indicate that cattle have the disease two to three months before the onset of clinical disease or after the onset of clinical disease. Given the limitations of the diagnostic tests available today, which are conducted on sections of the brain or spinal cord, certain tissues of cattle infected with BSE, such as distal ileum and small intestine, may contain BSE infectivity even though the diagnostic test will not show that the animal has the disease. Thus, exempting materials from cattle that test negative for BSE from the restrictions in this rulemaking will likely not provide the same level of protection as prohibiting those materials for use as human food.

Therefore, under this interim final rule, the use of specified risk materials from cattle is prohibited for human food regardless of whether the animal has been tested for BSE. FSIS requests comments on whether further consideration should be given to exempting cattle that have tested negative for BSE from the requirements contained in this interim final rule, and if so, what testing methods and protocols the Agency should accept as providing acceptable and reliable results.

Request for Comments

FSIS requests comments on the measures contained in this interim final rule, and specifically on whether the Agency has chosen measures that are most appropriate for preventing human exposure to the BSE agent in the United States.

Emergency Action

The fact that a cow in Washington State tested as positive for BSE on December 23, 2003, makes this rulemaking necessary on an emergency basis. As discussed above, BSE infectivity has been confirmed in the brain, eyes, trigeminal ganglia, tonsils, spinal cord, DRG and distal ileum. Furthermore, most of these tissues have demonstrated infectivity before experimentally infected animals developed clinical signs of disease. Thus, BSE infectivity in these tissues is not readily ascertainable. Therefore, FSIS has determined that it must take immediate action to ensure that materials that could present a significant risk to human health are excluded from the human food supply.

Under these circumstances, the FSIS Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest, and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**. FSIS will consider comments received during the comment period for this interim rule (*see* **DATES** above). After the comment period closes, the Agency will publish another document in the **Federal Register**. The document will include a discussion of any comments received in response to this interim rule and any amendments made as a result of those comments.

In an effort to ensure that establishments comply with this interim final rule upon publication in the **Federal Register**, FSIS will provide guidance to inspection program personnel regarding the implementation strategy. At a minimum, FSIS inspection program personnel will be directed to meet with management of each affected establishment to discuss how and when the establishment expects to complete its reassessment of its HACCP plan and to ensure that SRMs and MS (Beef) do not adulterate product.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. It has been determined to be economically significant for purposes of Executive Order 12866 and therefore, has been reviewed by the Office of Management and Budget (OMB).

The emergency situation surrounding this rulemaking makes timely compliance with Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable.

FSIS is currently assessing the potential economic effects of this action. When this work is complete, the Agency will publish a notice of availability in the **Federal Register** and will provide an opportunity for public comment.

Executive Order 12988

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5. must be exhausted before any judicial challenge of the application of the provisions of this interim final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this interim final rule have been submitted for emergency approval to the Office of Management and Budget (OMB).

Title: Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle.

Type of collection: New.

Abstract: In this interim final rule, FSIS is requiring that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle develop written procedures for the removal, segregation, and disposition of SRMs. FSIS is also requiring that these establishments maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and any corrective actions taken. These records are needed for FSIS to verify the effectiveness of an establishment's procedures.

Estimate of burden: FSIS estimates that it will take establishments approximately 8 hours to develop written procedures for the removal, disposition, and segregation of SRMs. FSIS estimates that an establishment will spend about five minutes a day developing an average of nine monitoring records, which includes documentation of any corrective actions taken, and an additional two minutes a day to file each record.

Respondents: Official establishments that slaughter cattle and official establishments that process the carcasses or parts of cattle.

Estimated Number of Respondents: 2,500.

Estimated Number of Responses per Respondent: 2,701.

Estimated Total Annual Burden on Respondents: 807,500 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th Street, SW., Washington, DC 20250 Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected, ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. To be most effective, comments should be sent to OMB within 30 days of the publication date of this interim final rule.

Government Paperwork Elimination Act (GPEA)

FSIS is committed to achieving the goals of the GPEA, which requires that Government agencies, in general, provide the public with the option of submitting information or transacting business electronically to the maximum extent possible. Under this interim final rule, records that document the implementation and monitoring of an establishment's procedures for the removal, segregation, and disposition of SRMs may be maintained on computers, provided that the establishment implements appropriate controls to ensure the integrity of the electronic data. Allowing establishments to comply with the required recordkeeping requirements will reduce data collection time, and information processing and handling by the regulated industry and FSIS.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this final interim final rule and are informed about the mechanism for providing their comments, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS Web page located at *http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/ stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

References

The following sources are referred to in this document. All have been placed on display in the FSIS Docket Room (address above) and may be seen by interested persons between 8:30 a.m. and 4:30 p.m., Monday through Friday. Materials that are not copyright protected may also be accessed on the FSIS Web site as related documents to this interim final rule.

1. Will, R.G., *et al.*, A new variant of Creutzfeldt-Jakob disease in the UK. Lancet 347, 921–925 (1996).
2. Collinge, J., *et al.*, Molecular analysis of prion strain variation and the aetiology of "new variant" CJD. Nature 383, 685–690 (1996).
3. Bruce, M.E., *et al.*, Transmission to mice indicates that "new variant" CJD is caused by the BSE agent. Nature 389, 498–501 (1997).
4. Scott, M.R., *et al.*, Compelling transgenentic evidence for transmission of bovine spongiform encephalopathy prions to humans. Proc Natl Acad Sci USA 96, 15137–12142 (1997).
5. Belay, E.D., *et al.*, Relationship between transmissible spongiform encephalopathies in animals and humans. In: Task Force Report of the Council for Agricultural Science and Technology. Washington, DC: Council for Agricultrual Science and Technology, October 2002, No. 136.
6. MMWR, Probable Variant Creutzfeldt-Jakob Disease in a U.S. Resident—Florida, 2002, 51(41):927–929 (October 18, 2002).
7. Department for Environment Food and Rural Affairs, United Kingdom, FSIS personal communication.
8. European Union Scientific Steering Committee (EU SSC), 2002. Update on the Opinion of TSE infectivity distribution in ruminant tissues (initially adopted by the scientific steering committee at its meeting of 10–11 January 2002 and amended at its meeting of 7–8 November 2002) following the submission of (1) a risk assessment by the German Federal Ministry of Consumer Protection Food and Agriculture, and (2) new scientific evidence regarding BSE infectivity distribution in tonsils; European Commission, Scientific Steering Committee, Health and Consumer Protection Directorate General.
9. Department for Environment Food and Rural Affairs, United Kingdom, DEFRA BSE Information, Youngest and oldest cases by year of onset-GB (Passive surveillance only), September 30, 2003.

10. Wells, G.A.H., *et al.*, Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy. Veterinary Record 135, 40–41 (1994).
11. Wells, G.A.H., *et al.*, Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): an update. Veterinary Record 142, 103–106 (1998).
12. Wells, G.A.H. Limited detection of sternal bone marrow infection in the clinical phase of experimental bovine spongiform encephalopathy. Veterinary Record 144, 292–294 (1999).
13. United Kingdom Food Standards Agency press release, Thursday, October 17, 2002.
14. European Union Scientific Steering Committee (EU SSC), 2001. Opinion of 10 December 1999 of the Scientific Steering Committee on the Human Exposure Risk (HER) via Food with Respect to BSE.
15. Analysis of 2002 FSIS Bovine AMR Products Survey Results, prepared by the United States Department of Agriculture, Food Safety and Inspection Service, February 2003. Available on the Internet at *http://www.fsis.usda.gov/oa/topics/AMRAnalysis.pdf.*
16. The Follow-up to the Beef AMR Product Survey of 2002: Follow-up Results and Actions for the Elimination of CNS (Spinal Cord) Tissues from AMR Products Derived from Beef Vertebrae, prepared by the Food Safety and Inspection Service, February 2003. Available on the Internet at *http://www.fsis.usda.gov/OA/topics/AMRSurvey.pdf.*
17. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States.
18. European Commission, 2003. "Report on the Monitoring and Testing of Ruminants for the Presence of Transmissible Spongiform Encephalopathy (TSE) in 2002," p. 49.
19. Doherr, M.G., *et al.*, Targeted screening of high-risk cattle populations for BSE to augment mandatory reporting of clinical suspects. Preventive Veterinary Medicine 51:1–2, 3–16 (2001).

List of Subjects

9 CFR Part 309

Ante-mortem inspection, Disposition of carcasses.

9 CFR Part 310

Post-mortem inspection, Disposition of carcasses.

9 CFR Part 311

Post-mortem inspection, Disposition of carcasses.

9 CFR Part 318

Entry into official establishments, reinspection and preparation of products.

9 CFR Part 319

Food grades and standards, Food labeling, Meat inspection.

■ For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III as follows:

PART 309—ANTE-MORTEM INSPECTION

■ 1. The authority citation for part 309 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

■ 2. Paragraph (b) of §309.2 is revised to read as follows:

§ 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.

* * * * *

(b) All seriously crippled animals and non-ambulatory disabled livestock shall be identified as U.S. Suspects and disposed of as provided in § 311.1 of this subchapter unless they are required to be classed as condemned under § 309.3. Non-ambulatory disabled livestock are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

* * * * *

■ 3. Section 309.3 is revised by adding a new paragraph (e) to read as follows:

§ 309.3 Dead, dying, disabled, or diseased and similar livestock.

* * * * *

(e) Non-ambulatory disabled cattle shall be condemned and disposed of in accordance with § 309.13.

PART 310—POST-MORTEM INSPECTION

■ 4. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 5. A new § 310.22 is added to read as follows:

§ 310.22 Specified risk materials from cattle and their handling and disposition.

(a) The following materials from cattle are specified risk materials:

(1) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older;

(2) The tonsils of all cattle; and

(3) The distal ileum of all cattle. To ensure effective removal of the distal ileum, the establishment shall remove the entire small intestine, and shall dispose of it in accordance with §§ 314.1 or 314.3 of this subchapter.

(b) Specified risk materials are inedible and shall not be used for human food.

(c) Specified risk materials shall be disposed of in accordance with §§ 314.1 or 314.3 of this subchapter.

(d) Procedures for the removal, segregation, and disposition of specified risk materials.

(1) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. The establishment shall incorporate such procedures into its HACCP plan or in its Sanitation SOP or other prerequisite program.

(2) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must take appropriate corrective action when either the establishment or FSIS determines that the establishment's procedures for the removal, segregation, and disposition of specified risk materials, or the implementation or maintenance of such procedures, have failed to ensure that such materials are adequately and effectively removed from the carcass of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section.

(3) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition of specified

risk materials in preventing the use of these materials for human food and shall revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials.

(4) *Recordkeeping requirements.* (i) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.

(ii) Records required by this section may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data.

(iii) Records required by this section shall be retained for at least one year and shall be accessible to FSIS. All such records shall be maintained at the official establishment 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

(e) The materials listed in paragraph (a)(1) of this section will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate that the materials are from an animal that was younger than 30 months of age at the time of slaughter.

PART 311—DISPOSAL OF DISEASED OR OTHERWISE ADULTERATED CARCASSES AND PARTS

■ 6. The authority citation for part 311 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§ 311.27 [Amended]

■ 7. Section 311.27 is amended as follows:

■ a. By inserting "of all livestock except for cattle" in the first sentence after "the carcass and all parts" and before "shall be kept for inspection".

■ b. By adding the following new sentence at the end of the paragraph: "The parts and carcasses of cattle slaughtered in the absence of an inspector shall not be used for human food."

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

■ 8. The authority citation for part 318 is revised to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 318.6 [Amended]

■ 9. Section 318.6 is amended as follows:

■ a. Paragraph (b)(1) is amended by removing the word "cattle" and adding the following new sentence at the end of the paragraph: "Casings from cattle may be used as containers of products provided the casings are not derived from the small intestine."

■ b. Paragraph (b)(4) is amended by adding the following new sentence at the end of the paragraph: "Detached spinal cords from cattle 30 months of age and older shall not be used as raw materials for edible rendering."

■ c. Paragraph (b)(8) is amended by adding the following new sentence at the end of the paragraph: "The small intestine of cattle shall not be used in any meat food products or for edible rendering."

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

■ 10. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

■ 11. Section 319.5 is amended as follows:

■ a. A new paragraph (b) is added to read as follows:

§ 319.5 Mechanically Separated Species.

* * * * *

(b) Mechanically Separated (Beef) is inedible and prohibited for use as human food.

* * * * *

Done at Washington, DC, on January 7, 2004.

Garry L. McKee,

Administrator.

[FR Doc. 04–625 Filed 1–8–04; 1:43 pm]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 318, and 320

[Docket No. 03–038IF]

RIN 0583–AC51

Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule and request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is issuing this interim final rule on meat produced by advanced meat recovery (AMR) systems. This new regulation is a prophylactic measure designed, in part, to prevent human exposure to the Bovine Spongiform Encephalopathy (BSE) agent by ensuring that AMR systems are not a means of introducing central nervous system tissue into product labeled as "meat." In addition to the measures related to BSE, FSIS is finalizing restrictions related to bone solids and bone marrow for livestock products. This rule articulates the criteria that FSIS will use to ensure that AMR products can be represented as "meat" and thus are not adulterated or misbranded. Finally, the Agency is requiring that Federally-inspected establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials (SRMs), including non-complying product from beef AMR systems. Establishments must incorporate these procedures into their HACCP plans or in their Sanitation SOPs or other prerequisite program. FSIS is issuing this document as an interim final rule because of the discovery of a BSE-positive cow in this country.

DATES: This interim final rule is effective January 12, 2004. Comments on this interim final rule must be received by April 12, 2004.

ADDRESSES: Submit written comments to: FSIS Docket Clerk, Docket #03–038IF, Room 102, Cotton Annex, 300 12th Street, SW., Washington, DC 20250–3700. Reference materials cited in this document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday. Reference materials that are not copyrighted will also be available on the FSIS Web site at *http://www.fsis.usda.gov.* All comments will be available for inspection in the FSIS Docket Room or on the FSIS Web site at *http://www.fsis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Executive Associate, Policy Analysis and Formulation, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Table of Contents

Proposed Rules

Federal Register
Vol. 68, No. 213
Tuesday, November 4, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 95

[Docket No. 03–080–1]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and are proposing to add Canada to this category. We are also proposing to allow the importation of certain live ruminants and ruminant products and byproducts from such regions under certain conditions. We believe this action is warranted because it would continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on certain commodities from Canada and other regions that qualify as BSE minimal-risk regions.

DATES: We will consider all comments that we receive on or before January 5, 2004.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–080–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–080–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 03–080–1" on the subject line.

You may read the risk assessment, environmental assessment, economic analysis, and any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the Department) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a progressive neurological disorder of cattle that results from infection by an unconventional transmissible agent and is not known to exist in the United States. The disease has been difficult to define experimentally with precision, although risk factors that are independent of the causative agent have been identified and can be mitigated. Much of the available data originated from epidemiological observations and not from controlled studies. Controlled studies are often difficult to conduct because of limitations in experimental models and the length of time necessary to conduct the studies, which may require years. Currently, the most accepted theory is that the agent is a modified form of a normal cell surface component known as prion protein, although other types of agents have been implicated, including virinos. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is extremely resistant to heat and to normal sterilization processes. It does not evoke any demonstrated immune response or inflammatory reaction in host animals.

Despite the difficulty in defining BSE experimentally with precision, risk factors for BSE that can be mitigated have been identified. These factors are based on technical knowledge and disease epidemiology and do not require definition of the nature of the agent. We believe that risk mitigation measures that address the risk factors for BSE will be effective regardless of the precise nature of the BSE agent.

It appears that BSE is spread primarily through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Ruminants in the United States could be exposed to the disease if materials carrying the BSE agent—such as certain meat, animal products, or animal byproducts from ruminants—were imported into the United States and were fed to ruminants in this country. BSE could also be introduced into the United States if ruminants with BSE were imported into the United States.

Because of these risks, the regulations prohibit the importation of live ruminants and certain ruminant products and byproducts from two categories of regions: (1) Those regions in which BSE is known to exist, which are listed in § 94.18(a)(1) of the regulations; and (2) those regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance. These regions of "undue

risk" are listed in § 94.18(a)(2) of the regulations.

The prohibitions on the importation of animals, meat, and other animal products into the United States from regions listed in § 94.18(a)(1) or (a)(2) are set forth in 9 CFR parts 93, 94, 95, and 96. Section 93.401 prohibits the importation of any ruminant that has been in these regions. Except for certain controlled transit movements, paragraph (b) of § 94.18 prohibits the importation of fresh (chilled or frozen) meat, meat products, and most other edible products of ruminants that have been in any of the regions. Paragraph (c) of § 94.18 restricts the importation of gelatin derived from ruminants that have been in any of the regions. Section 95.4 prohibits or restricts the importation of certain byproducts from ruminants that have been in any of the regions, and § 96.2 prohibits the importation of casings, except stomach casings, from ruminants that have been in any of the regions.

Essentially then, under the current regulations, there are three categories of regions with regard to BSE. Currently, a region is considered either: (1) A region free of BSE; (2) a region in which BSE is known to exist; or (3) a region that presents an undue risk of BSE. Imports from free regions are generally not subject to restrictions because of BSE. Imports from BSE-affected regions and those that present an undue risk are governed by the same set of restrictions.

We believe it is appropriate to recognize an additional category of regions with regard to BSE—the BSE minimal-risk region. This category would include (1) those regions in which a BSE-infected animal has been diagnosed, but in which measures have been taken that make it unlikely that BSE would be introduced from the region into the United States, and (2) those regions that cannot be considered BSE free even though BSE has not been detected, but that have taken sufficient measures to be considered minimal risk. For instance, a region listed in § 94.18(a)(2) as an "undue risk" region might have increased its levels of surveillance or import restrictions to the point that the risk of BSE introduction from that region becomes unlikely, but not yet have had mitigation measures in place long enough to be considered BSE-free.

In § 94.0, we would define *bovine spongiform encephalopathy (BSE) minimal-risk region* by listing the factors we would consider in determining the region's risk status. In a new § 94.18(a)(3), we would list the regions that the Administrator has approved for this designation. At this time, we are proposing to designate one country, Canada, as a BSE minimal-risk region according to the newly proposed factors. (These factors, and the reasons why we believe Canada meets them, are discussed in detail below.) In § 94.18(a)(4), we would explain that a region may request to be designated a BSE minimal-risk region by following the procedures set forth in our regulations in 9 CFR part 92, "Importation of Animals and Animal Products: Procedures for Requesting Recognition of Regions."

Canada as a BSE Minimal-Risk Region

On May 20, 2003, the Canadian Food Inspection Agency reported a case of BSE in a beef cow in northern Alberta. Therefore, in order to prevent the introduction of BSE into the United States, we published an interim rule on May 29, 2003 (68 FR 31939–31940, Docket No. 03–058–1), effective retroactively to May 20, 2003, to add Canada to the list of regions where BSE exists. As a result of that action, the importation of ruminants that have been in Canada and the importation of meat, meat products, and certain other products and byproducts of ruminants that have been in Canada are prohibited or restricted.

Following the detection of the BSE-infected cow, Canada conducted an epidemiological investigation of the BSE occurrence, and took action to guard against any spread of the disease, including the quarantining and depopulation of herds and animals determined to possibly be at risk for BSE. Subsequently, Canada asked APHIS to consider reestablishing the importation of ruminants and ruminant products into the United States from that country, based on information made available to APHIS regarding Canada's veterinary infrastructure, disease history, practices for preventing widespread introduction, exposure, and/or establishment of BSE, and measures taken following detection of the disease.

In this document, we are proposing to list Canada as a BSE minimal-risk region based on an analysis we conducted of the conditions considered for such a designation and the information available to us regarding how Canada meets those conditions. The risk document, "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States," also identifies the measures we believe are necessary to mitigate any BSE risk that specific commodities imported from Canada might present to the United States (discussed in this proposed rule, below, under the heading "Importation of Ruminant Commodities from a BSE Minimal-Risk Region").

You may view the analysis in our reading room (information on the location and hours of the reading room is provided under the heading **ADDRESSES** at the beginning of this proposed rule). You may also request a copy by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the analysis when requesting copies. You may also view the analysis on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov*. At the APHIS Web site, click on the "Hot Issues" button. On the next screen, click on the listing for "Bovine Spongiform Encephalopathy (BSE)." On the next screen, click on the listing for "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States."

In this proposed rule, we first discuss the factors we would consider in classifying a region as a BSE minimal-risk region. We would consider these factors in considering requests from any region to be classified as a BSE minimal-risk region. We then discuss why we believe Canada qualifies as a BSE minimal-risk region. Following that, we discuss mitigations that we would apply to specific commodities from Canada.

Proposed Factors for BSE Minimal-Risk Regions

APHIS has developed a list of factors we would use to evaluate the BSE risk from a region and classify a region as a BSE minimal-risk region. We would use these factors as a combined and integrated evaluation tool. We are proposing to base the classification on an evaluation of the sum total of these factors, focusing on overall effectiveness of control mechanisms in place (*e.g.*, surveillance, import controls, and a ban on the feeding of ruminant protein to ruminants). For regions in which BSE has been diagnosed, we would base our evaluation on the overall effectiveness of such control mechanisms in place at the time BSE was diagnosed in the region, and on actions taken after the diagnosis (*e.g.*, an epidemiological investigation of the occurrence). For regions in which BSE has not been diagnosed, we would base our evaluation on the adequacy of surveillance mechanisms to detect disease, efficacy of a feed ban, and effectiveness of programs in place to prohibit entry into and establishment of disease in the region. This approach differs from some of the numerical criteria specified by the Office

International des Epizooties (OIE) in its recommendations for a BSE minimal-risk country or zone. (The OIE recommendations are recognized by the World Trade Organization as international recommendations for animal disease control.)

For example, according to OIE recommendations, a ban on the feeding of ruminant protein to ruminants should have been in place for a minimum of 7 years for a region to meet the criteria for BSE minimal risk, even though there is a significant level of variability in current estimates of the BSE incubation period, which should govern the recommended length of time of an effective feed ban. According to this criterion, a region could fail to be classified as a BSE minimal-risk region because it had not had a feed ban in effect for the precise period of time specified, even if it has excelled in surveillance and control mechanisms. We believe it is more appropriate to evaluate the overall combined effect of the factors described below when assessing the BSE risk level of a region.

Definition of Bovine Spongiform Encephalopathy Minimal-Risk Region

We propose to define *bovine spongiform encephalopathy (BSE) minimal-risk region* in § 94.0 to mean a region that:

1. Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

a. Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;

b. Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE; and

c. A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

2. In regions where BSE was detected, conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

3. In regions where BSE was detected, took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

Each element of this definition is explained below.

1. The region maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease.

This factor is important in determining those regions in which a BSE outbreak is unlikely to occur, or, if an outbreak does occur, in which it is likely to be limited. If a region maintains controls designed to minimize BSE introduction or exposure of animals, and, in those regions where BSE has been detected, if the region had such controls in place at the time of detection, it is more likely to present minimal risk than a region that does not have such controls in place. According to our definition of a BSE minimal-risk region, such measures would include importation restrictions, surveillance, and a feeding ban, as follows:

1a. Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE.

This factor addresses whether the region faces a high risk of initial or recurrent BSE outbreaks from multiple importations of animals or products that may spread BSE. In those regions in which BSE has been detected, it addresses whether the region's BSE outbreak was more likely the result of a point failure in its import controls or possible exposure prior to the implementation of such import controls. Because the incubation period for BSE is generally measured in years, the finding of a case of BSE reflects an exposure that occurred several years in the past.

A region that has prohibited the importation of high-risk animals and products from regions that are affected with or pose an undue risk of BSE will have minimized its possible exposure to the disease. Conversely, a region that continues to import high-risk commodities until a case of BSE is diagnosed has continued exposure and presents a more significant risk. Whether commodities are considered low-risk or high-risk can be based on the commodities' inherent lack of risk, the low risk level of the exporting region, and/or controls on the movement and use of the commodities after entry.

1b. Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE.

This factor addresses whether BSE outbreaks are or would be likely to be quickly and reliably identified in a region, helping support a minimal-risk designation, or whether lack of effective surveillance suggests the possibility that BSE-infected animals may be overlooked and the scale of a BSE problem may be greater than is officially recognized.

As noted above, the OIE recommendations are recognized by the World Trade Organization as international recommendations for animal disease control. The OIE Code provides guidelines for surveillance and monitoring systems for BSE, identifying the minimum number of annual investigations recommended based on the adult cattle population of a country.

1c. A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

The primary source of BSE infection appears to be feed contaminated with the infectious agent. Scientific evidence [1] shows that feed contamination results from the incorporation of ingredients that contain ruminant protein derived from infected animals. Standard rendering processes do not completely inactivate the BSE agent. Therefore, rendered protein such as meat-and-bone meal derived from infected animals may contain the infectious agent. Bans prohibiting incorporation of mammalian or ruminant protein into ruminant feed are imposed to mitigate risk.

This factor distinguishes between regions with effective feed bans and those without them. In a region in which BSE has been detected, if an animal with BSE was born after a feed ban was implemented, it is a sign that the feed ban may not be effectively enforced.

2. In a region in which BSE has been detected, the region conducted an

[1] Wilesmith, J.W., Wells, G.A.H., Cranwell, M.P., and Ryan, J.B.M.; 1988; Bovine spongiform encephalopathy; epidemiological studies; Veterinary Record; 123, pg 638–644.

Wilesmith, J.W., Ryan, J.B.M. and Atkinson, M.J.; 1991; Bovine spongiform encephalopathy; epidemiological studies of the origin; Veterinary Record; 128, pg 199–203.

Wilesmith, J.W., Ryan, J.B.M. and Hueston W.D.; 1992; Bovine spongiform encephalopathy: Case control studies of calf feeding practices and meat-and-bone meal inclusion in proprietary concentrates; Res Vet Sci; 52, pg 325–331.

epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

This factor addresses whether a region adequately investigates a case of BSE to determine if any of the risk factors have changed. If there has been any significant change in risk factors, there might be the possibility of increased incidence of BSE. Such an investigation would include, at the minimum, a traceback from the BSE-infected animal to determine possible herds of origin of the animal, a traceforward of any animals that moved from the BSE-affected herd, a traceforward of feed or rendered material that was derived from the carcass of the infected animal, and an investigation to determine the most likely source of the animal's exposure to BSE.

3. In a region in which BSE has been detected, the region took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

This factor addresses whether a region implements all necessary risk mitigation measures to prevent further exposure to BSE. It distinguishes between those regions that thoroughly analyze their situation and address any problems from those that do not take mitigation measures and thus prolong possible exposure to BSE. Depending on the conclusions of the risk analysis conducted following the diagnosis of BSE, additional risk mitigation measures could include a broad eradication program, increased surveillance, or additional import restrictions.

Evaluating Canada as a BSE Minimal-Risk Region

We considered the above factors in combination in evaluating whether Canada qualifies as a BSE minimal-risk region, and discuss below the actions Canada took and continues to take regarding each of the factors.

Import Restrictions

Canada has maintained stringent import restrictions since 1990,[2] prohibiting the importation of live ruminants and most ruminant products from countries that had not been recognized as free of BSE by either the United States, Canada, or Mexico, which have an agreement to recognize country evaluations conducted by any of the three countries, using the same standards. Canada prohibited the importation of live cattle from the United Kingdom and the Republic of Ireland starting in 1990, and subsequently applied the same prohibitions to other countries as those additional countries identified native cases of BSE. In 1996, Canada made this policy even more restrictive and prohibited the importation of live ruminants from any country that had not been recognized as free of BSE. Some animals were imported into Canada from high-risk countries prior to the imposition of these import restrictions. A total of 182 cattle were imported into Canada from the United Kingdom between 1982 and 1990. Similar to actions taken in the United States, efforts were made in Canada to trace these animals. In late 1993, after Canada identified a case of BSE in one of the imported bovines, all cattle imported from the United Kingdom or the Republic of Ireland that remained alive at that time were killed.

Import restrictions have also been imposed on ruminant products, including import restrictions on meat-and-bone meal that have been in place since 1978. In general, Canada has prohibited the importation of most meat-and-bone meal from countries other than the United States, Australia, and New Zealand. Limited amounts of specialty products of porcine or poultry origin were allowed to be imported into Canada under permit for use in aquaculture feed products. No meat-and-bone meal for livestock feed-associated uses has been imported, except from the United States, Australia, and New Zealand.

Surveillance

Canada has conducted surveillance for BSE since 1992. The OIE Code, Appendix 3.8.4, provides guidelines for surveillance and monitoring systems for BSE, identifying the minimum number of annual investigations recommended based on the adult cattle population of a country. To meet this recommendation, Canada would have to test a minimum of 336 samples annually, based on a population of 5.5 million adult cattle. Canada exceeds this recommendation, and has tested more than this minimum number of samples for the past 7 years. Additionally, Canada exceeds OIE recommendations by conducting active targeted surveillance. (Active targeted surveillance involves sampling animals with risk factors for BSE, even if the animals have not shown clinical signs of disease.)

Feed Ban

Canada implemented a feed ban in 1997 that prohibits the feeding of most mammalian protein to ruminants. This ban exceeds what we consider the minimal necessary measure of banning the feeding of ruminant material to ruminants. Under the ban in Canada, mammalian protein may not be fed to ruminants, with certain exceptions. These exceptions include pure porcine or equine protein, blood, milk, and gelatin. The feed ban is essentially the same as the feed ban in place in the United States.

APHIS believes the length of the feed ban in Canada is sufficient to classify that country as a minimal-risk region for BSE. In comparison, classification as a minimal-risk country or zone by OIE criteria requires that a feed ban be in place for 8 years. This value may be set at a conservative level to account for the wide range that has been reported for the incubation period of BSE. Because of the variability in the incubation period for BSE, APHIS chose not to specify an amount of time that a feed ban needed to be in place in a minimal-risk region. Rather, we considered the sum total of the control mechanisms (*e.g.*, effectiveness of surveillance, import controls, and feed ban) in place at the time of the diagnosis of BSE and the actions taken subsequently (*e.g.*, epidemiological investigations and depopulation), thereby allowing the actions Canada took with regard to the other factors to compensate for a shorter feed ban. As an example, as discussed above, the level of surveillance in Canada, and the fact that it has been active and targeted, has exceeded OIE recommendations.

Canadian Government authorities inspect rendering facilities, feed manufacturers, and feed retailers to ensure compliance with the feed ban. Rendering facilities are regulated under an annual permit system, and compliance with the regulations is verified through at least one inspection each year. Feed manufacturers or mills, feed retailers, and farms have been inspected on a routine basis. These inspections have shown a high level of compliance. As noted above, Canada has maintained an effective ban on feeding mammalian protein to ruminants, with requirements similar to the feed ban in place in the United States, since 1997. The animal in which BSE was diagnosed in May 2003 was an 6-year-old native-born beef cow in the Province of Alberta that was born before the implementation of the feed ban.

[2] Canadian Food Inspection Agency (CFIA), December 2002; Risk Assessment on Bovine Spongiform Encephalopathy in Cattle in Canada.

Morley, R.S., Chen, S., Rheault, N.; 2003; Assessment of the risk factors related to bovine spongiform encephalopathy; Rev. Sci. Tech. OIE; 22(1); pg 157–178.

Epidemiological Investigation

Canada conducted an extensive epidemiological investigation after the one case of BSE in May 2003. This investigation included detailed tracebacks to identify possible herds of origin of the infected animal, traceforwards from the infected herd, and traceforwards of any possible feed or rendered material derived from the carcass of the infected animal. Fifteen premises were quarantined as part of the traceback and traceforward investigations, and cattle on the quarantined premises were slaughtered. Additionally, cattle that were determined to have moved from a quarantined herd to another herd were slaughtered.

The investigation included any possible exposure from the use of rendered material or feed that could have been derived from the carcass of the infected cow. Using a broad definition to include all possible exposures, the rendered material could have been distributed to approximately 1,800 sites, including sites with no ruminants. These included 600 facilities that receive bulk shipments of either rendered protein or feed, and 1,200 individual producers or consumers who purchased finished feed by the bag. A survey was conducted of those entities that were at some risk of having received such rendered material or feed. This survey suggested that 99 percent of the sites surveyed experienced either no exposure of cattle (96 percent of the sites) to the feed or only incidental exposure (3 percent of the sites). The remaining 1 percent represented limited exposures, such as cattle breaking into feed piles, sheep reaching through a fence to access feed, and a goat with possible access to a feed bag.

The investigation included a consideration of several possibilities for the source of the infected cow's exposure to BSE. Although it has not been confirmed, it is assumed, based on the age of the cow, that the infected cow was exposed through contaminated feed. The infected animal was born prior to the implementation of a feed ban within Canada and could have had exposure to contaminated feed at an early age.

The renderers and feed mills associated with the investigation had records of good compliance with the feed ban. The on-farm inquiries demonstrated a very small probability of exposure of ruminants to prohibited feed. Although the possibility exists that the original source of the BSE agent could have been imported, there was no evidence that this was due to an illegal import. The BSE agent could have been from animals imported from the United Kingdom prior to import restrictions established in 1990. The surveillance program was sufficient to confirm the continued existence of adequate measures to prevent further introduction or spread of BSE.

Additional Risk Mitigation Measures

Following the detection of BSE in Canada, a broad eradication program was followed during the epidemiological investigation, in which more than 2,700 head of cattle were culled. As part of the culling activity, more than 2,000 animals 24 months of age or older were tested (those animals less than 24 months of age were not tested), with no further evidence of BSE found in any of these animals.

Importation of Ruminant Commodities From a BSE Minimal-Risk Region

Because we believe regions, such as Canada, that qualify as BSE minimal-risk regions based on the factors described above, would pose a minimal risk of introducing BSE into the United States, we believe it is warranted to allow the importation from such regions of some animals and animal products and byproducts that are prohibited importation from regions in which BSE exists and regions that present an undue risk of BSE. However, because BSE is a difficult disease to define experimentally with precision, epidemiological evidence suggests that risk factors are specific to the commodity, and multiple risk sources may be associated with a given commodity, we believe it is necessary to also apply individual risk mitigation measures to specified commodities intended for importation from BSE minimal-risk regions.

For example, as noted above and discussed further below, contaminated feed appears to be the most likely pathway of BSE transmission. However, it has not been established with certainty that contaminated feed is the only pathway. Furthermore, we cannot assume complete compliance with a ban on the feeding of ruminant protein to ruminants, which is the most effective mitigation for contaminated feed. Therefore, we believe it is necessary to apply certain other mitigation measures, in addition to implementation of a feed ban, to reduce the risk of the introduction of BSE into the United States. Each of these proposed mitigation measures is discussed below.

We are proposing to add the conditions for importing specified ruminant commodities from a BSE minimal-risk region to the regulations in 9 CFR parts 93, 94, and 95. The measures appropriate for specific commodities intended for importation would be determined by the presence or absence of factors that make it more or less likely the commodity might be contaminated or infected with the BSE. These factors are discussed in the following paragraphs.

Feed Source and Exposure

Oral ingestion of feed contaminated with the abnormal BSE prion protein is the only documented route of field transmission of BSE.[3] Thus, animals that have not ingested contaminated feed are unlikely to harbor the agent, so feed exposure influences risk. Animals, and the products derived from those animals, are unlikely to have infectious levels of the agent and will present a lower risk if the animals were (a) born after the implementation of an effective feed ban or (b) not fed risk material (*e.g.*, wild animals or farmed animals that are not fed feeds containing meat-and-bone meal).

The risks associated with feed source and exposure can be mitigated by accepting for import only animals or products derived from animals that have not been fed commercial feed that is likely to be contaminated with infectious levels of the agent.

Animal Age

Levels of infectious agent in certain tissues vary with the age of an animal, so the age of the animal influences risk. Pathogenesis studies, where tissues obtained from orally infected calves were assayed for infectivity, have illustrated this.[4] Infectivity was not detected in most tissues until at least 32 months post-exposure. The exception to this is the distal ileum (a part of the intestines), where infectivity was

[3] Prince, M.J., *et al.*; 2003; Bovine Spongiform Encephalopathy; Rev. sce. tech. OIE; 22 (1), pg 37–60.

Wilesmith *et al.*; 1988; 1991; 1992.

[4] Wells, G.A.H., *et al.*; 1994; Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy; Veterinary Record; 135 (2), pg 40–41.

Wells, G.A.H., *et al.*; 1998; Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): An update; Veterinary Record; 142, pg 103–106.

European Union Scientific Steering Committee (EU SSC), 2002; Update of the opinion on TSE infectivity distribution in ruminant tissues (initially adopted by the Scientific Steering Committee at its meeting of 10–11 January 2002 and amended at its meeting of 7–8 November 2002) following the submission of (1) a risk assessment by the German Federal Ministry of Consumer Protection, Food, and Agriculture, and (2) new scientific evidence regarding BSE infectivity distribution in tonsils; European Commission, Scientific Steering Committee, Health and Consumer Protection Directorate General.

confirmed from the experimentally infected cattle as early as 6 months post-exposure. In this proposed rule, we take these findings into account when establishing measures to mitigate the risk of infectious levels of the BSE agent being present in animals and animal products imported from a BSE minimal-risk region. For example, with regard to bovines, because BSE infectivity has not been found in most bovine tissues until at least 32 months post-exposure, we believe that by requiring that bovines imported into the United States from BSE minimal-risk regions be less than 30 months of age, the risk of the BSE agent being present at infectious levels in most tissues in the animal is minimized. The 30-month age limit is accepted internationally in BSE standards set by various countries and is consistent with OIE recommendations. Similarly, the proposed regulations would require that imported meat from bovines be derived from animals less than 30 months of age when slaughtered. However, because of evidence that the BSE agent may be present at infectious levels in the distal ileum of infected bovines as early as 6 months post-exposure, we would require that the intestines of bovines imported into the United States be removed at slaughter, and that meat imported from bovines from BSE minimal-risk regions be derived from animals from which the intestines were removed at slaughter.

Although the risks associated with age can be mitigated by accepting for import only animals or commodities derived from animals of an age where even high risk tissues (discussed below) are unlikely to have infectious levels of the BSE agent, restrictions applicable to age alone may not always be possible or sufficient. For instance, in the case of wild cervids, because it is not always possible to determine the age of the cervids, we believe that alternative risk measures, discussed below, are necessary.

Research demonstrates that the incubation period for BSE is apparently linked to the infectious dose received—*i.e.*, the larger the infectious dose received, the shorter the incubation period (EU SSC 2002). While some cases of BSE have been found in animals less than 30 months of age, these are relatively few and have occurred primarily in countries with significant levels of circulating infectivity (*i.e.*, where infected ruminants are used for feed for other ruminants, which in turn become infected). The conditions, discussed above, for qualifying for a BSE minimal-risk region guard against such circulating infectivity.

Similar observations regarding the importance of the size of the infectious dose were made in sheep and goats (EU SSC 2002). In these animals, infectivity could not be demonstrated in most tissues until at least 16 months post-exposure to the agent.

In summary, infected cattle over 30 months of age or sheep and goats over 16 months of age may have levels of the abnormal prion in affected tissues that are sufficient to infect other animals fed protein derived from these tissues. Infected animals less than 30 months of age or sheep and goats less than 16 months of age are unlikely to have infectious levels of the prion protein (EU SSC 2002; Wells, *et al.*; 1994; Wells, *et al.*; 1998).

Animals that were born before the feed ban but were not fed risk material, such as wild ruminants or domestic livestock in the minimal-risk region that were fed solely materials that are extremely unlikely to contain the infectious agent, are unlikely to contain infectious levels of BSE.

Tissue Localization

Some bovine tissues have demonstrated infectivity, whereas others have not. Tissues that have demonstrated infectivity, and thus are likely to contain the infectious agent in infected cattle, are brain, tonsil, spinal cord, eyes, trigeminal ganglia, dorsal root ganglia, and distal ileum. (Please note that, as discussed above, the age of an animal is a key factor in whether the animal is likely or unlikely to be infected. Cattle less than 30 months of age unlikely to be infected with BSE, and, therefore, even the tissues listed above, except for the distal ileum, from such animals are unlikely to contain the infectious agent.) Affiliated tissues or structures such as skull or vertebral column are considered risk materials because of the difficulty in separating out small tissues such as dorsal root ganglia from the vertebral column. Possibilities for cross contamination from risk materials must be considered also. However, even cattle carrying the infectious agent are unlikely to carry that agent in tissues that have not demonstrated infectivity (*e.g.*, muscle, liver, skin, hide, milk, embryos) or products derived from these tissues [5] (also, Wells, *et al.*; 1994; Wells, *et al.*; 1998).

The risks associated with tissue localization can be mitigated by accepting only tissues that are unlikely to have infectious levels of the agent, due to the nature of the tissue or the age of the animal (in cattle under 30 months of age, only the distal ileum is such a risk material), or commodities derived from those tissues.

Source Species

Tissue distribution of the agent varies with species. Results from experimental infections of sheep have shown that the BSE prion is distributed more widely in sheep tissues than in cattle.[6] This distribution is similar to the distribution of scrapie (a transmissible spongiform encephalopathy present in the United States) infections in sheep. In these infections, the agent may be found in the lymphoreticular system and in peripheral nerves (Foster *et al.*; 1996; Foster *et al.*; 2001).

However, no natural infections with BSE have yet been confirmed in sheep, although testing is ongoing in Europe. Similarly, no natural infections have been confirmed in goats, although actual experiments have not been conducted in the species. In the absence of actual data, distribution of the agent in goat tissues has been assumed to be similar to distribution of the agent in sheep tissues, based on the fact that scrapie acts very similarly in sheep and goats.

Similarly, natural infection of cervids (deer and elk species) with BSE has not been documented, and no challenge studies on cervid susceptibility to BSE have been conducted. In the absence of actual data, it is assumed that distribution of any BSE agent in cervid tissues would be similar to the distribution of the chronic wasting disease agent in cervid tissues, which is a naturally occurring transmissible spongiform encephalopathy.

Prevalence of BSE

The possible prevalence of disease in the region of origin will influence the risk. Prevalence of the disease will be lower in a country with adequate prevention and control measures; thus, animals from such a region will be at lower risk of being exposed to infection. The risks associated with prevalence can be mitigated by accepting commodities only from a country with low prevalence that can be classified as minimal or low risk.

[5] Wrathall, A.E., *et al.*; 2002; Studies of embryo transfer from cattle clinically affected by bovine spongiform encephalopathy (BSE): Veterinary Record; 150; pg 365–378.

[6] Foster, J.D., *et al.*; 1996; Detection of BSE infectivity in brain and spleen of experimentally infected sheep; Veterinary Record; 139; pg 912–915.

Foster, J.D., *et al.*; 2001; Distribution of the prion protein in sheep terminally affected with BSE following experimental oral transmission; J. Gen Virol.; 82; pg 2319–2326.

Importation of Live Ruminants

We believe the categories of ruminants discussed below from BSE minimal-risk regions are unlikely to be a source of infectivity of the BSE agent if the conditions specified below are met, and we propose to allow for such importation under those conditions in a new § 93.436. In each case where we are proposing to allow importation, the animals would have to arrive through a designated port of entry as listed in current § 93.403(b) (designated ports of entry for ruminants from Canada), or through some other port that has been designated as a port of entry by the Administrator under § 93.403(f). If, in the future, we add other countries to the list of BSE minimal-risk regions in § 94.18(a)(3), we would adjust the list of designated ports accordingly.

In those cases where a ruminant is imported into the United States, and subsequently does not meet one of the conditions set forth in § 93.436 (*e.g.*, animals that die before reaching the slaughtering establishment; animals that are moved from a feedlot in this country to slaughter after they are 30 months of age), the regulations would provide that the animal must be disposed of in a manner approved by the Administrator.

Bovines Less Than 30 Months of Age for Immediate Slaughter

Section 93.436, paragraph (a), would allow the importation of bovines for immediate slaughter under the following conditions:

- The bovines are less than 30 months of age and are moved directly as a group from the port of entry to a recognized slaughtering establishment (the definition of recognized slaughtering establishment is set forth in § 93.400) for immediate slaughter as a group. (Under the definition of *immediate slaughter* in § 93.400, the bovines must be slaughtered within 2 weeks of the date of entry. In § 93.400, we would add a definition of *as a group* to mean collectively, in such a manner that the identity of the animals as a unique group is maintained.)
- The bovines are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The bovines are accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so, that certifies the above conditions have been met.
- The bovines are moved as a group from the port of entry to the slaughtering establishment in conveyances sealed at the port of entry with seals of the United States Government, which are broken only at the slaughtering establishment by a USDA representative, and the shipment is accompanied by an APHIS Veterinary Services (VS) Form 17–33, Animals Imported for Immediate Slaughter.
- At the slaughtering establishment, the bovines are slaughtered as a group and each animal's intestines are removed.
- The intestines removed from the bovines are disposed of in a manner approved by the Administrator.

We believe the conditions described above, combined with the fact the exporting region is one of minimal risk for BSE, make it very unlikely that meat derived from bovines meeting those conditions would contain the BSE agent. The requirement that the bovines imported from a BSE minimal-risk region be less than 30 months of age would make it unlikely they would have infectious levels of the prion protein. The requirements that the bovines be moved to slaughter in a sealed conveyance and be slaughtered as a group are designed to ensure that the animals are not diverted while being moved to slaughter and that the intestines are removed at slaughter from all bovines imported from the minimal-risk region. If any bovines not from the minimal-risk region are commingled with the group of bovines from the minimal-risk region at the slaughtering establishment, then those added animals would be treated as if they were from the minimal-risk region and their intestines would have to be removed and disposed of in accordance with our proposed provisions. The requirement that the bovines be slaughtered at a recognized slaughtering establishment (as defined in § 93.400) would ensure the animals are slaughtered at a facility approved by APHIS where slaughtering operations are regularly carried on under Federal or State inspection. The requirement that the intestines be removed from the animal at slaughter and be disposed of in a manner approved by the Administrator would minimize the possibility that such materials will be fed to ruminants. We believe it is necessary to provide the Administrator discretion in the specific means of disposal used, to allow for the use of different but equally effective methods of disposal.

Bovines Less Than 30 Months of Age Moved to a Designated Feedlot and Then to Slaughter

We would apply the slaughtering conditions described above to bovines imported for slaughter in the United States after first being contained at a designated feedlot in this country. However, instead of being moved directly from the port of entry to a recognized slaughtering establishment, such animals would first be moved directly, as a group, to a designated feedlot for feeding, and then directly to a recognized slaughtering establishment. In § 93.400, we would define *designated feedlot* to mean a feedlot indicated on the declaration required under § 93.407 as the destination of the ruminants imported into the United States. Under current § 93.407, the importer of ruminants (or the importer's agent) must present a declaration at the port of entry that provides information about the ruminants, their origin, and their destination. For identification purposes, prior to being imported into the United States, each bovine would have to have been tattooed inside one ear with letters identifying the exporting country. Bovines from Canada would have to be tattooed with the letters "CAN."

Therefore, § 93.436(b) would allow the importation of bovines for feeding under the following conditions:

- The bovines are not known to have been fed ruminant protein, other than milk protein, during their lifetime and are less than 30 months of age when imported into the United States.
- The inside of one ear on each animal is permanently and legibly tattooed with letters identifying the exporting country.
- The bovines are accompanied by authorized official certification, as described above, that the above conditions have been met.
- The bovines are moved directly from the port of entry as a group to the designated feedlot and the shipment is accompanied by an APHIS Form VS 1–27, Permit for Movement of Restricted Animals.
- The bovines are moved directly from the designated feedlot to a recognized slaughtering establishment for slaughter, where each animal's intestines are removed. The shipment is accompanied by APHIS Form VS 1–27.
- The intestines removed from the bovines are disposed of in a manner approved by the Administrator.
- The bovines are less than 30 months of age when slaughtered.

Unlike the requirement for bovines moved directly to immediate slaughter, we would not require that the animals

be moved from the port of entry to the designated feedlot in sealed conveyances. The only region we are proposing at this time to classify as BSE minimal-risk is the country of Canada. Under the current APHIS regulations and policy, bovines imported from Canada for movement directly to immediate slaughter do not have to be accompanied by the health certificate required under § 93.405 that attests to the animal's health history with regard to various diseases and pests. However, the bovines must be moved to slaughter in a sealed conveyance. **(Please note:** The regulations in part 93 use the term "cattle" rather than "bovines." However, in § 93.400, *cattle* is defined as animals of the bovine species.) Because of the requirement for direct movement to slaughter in a sealed conveyance, there is little danger the bovines will be diverted on their way to the slaughtering establishment. Those requirements would remain unchanged by this proposed rule, although animals for immediate slaughter would have to be accompanied with the certification with regard to BSE specified in this proposal.

Under the current regulations, however, bovines imported from Canada for other than immediate slaughter do have to be accompanied by a certificate attesting to their health history with regard to various diseases, in order to ensure they do not spread such diseases to other livestock in this country. Because of their acceptable health history, it has not been necessary to require that the animals be moved in a sealed conveyance. This requirement for a health certificate would remain in place for bovines imported from Canada for feeding before slaughter (and be joined with the certification with regard to BSE specified in this proposal). Because of this health certification, and because, with regard to BSE, the bovines would have to be tattooed with the letters CAN, possible diversion is not an issue and we do not consider it necessary to begin to require that feeder bovines be moved from the U.S. port of entry to the designated feedlot in a sealed conveyance.

Additionally, we are not requiring that the bovines be moved from the designated feedlot to slaughter as a group. A shipment of bovines that arrives at a feedlot may contain animals of varying ages. Some will be ready for shipment to slaughter before others. However, we would require that all animals moved from the designated feedlot be moved directly to slaughter, where they would be identifiable as a shipment from a minimal-risk region by the required ear tattoo.

Sheep or Goats Less Than 12 Months of Age for Immediate Slaughter

Section 93.436, paragraph (c), would allow the importation of sheep or goats under the following conditions:

- The sheep or goats are less than 12 months of age at the time of importation.
- The sheep or goats are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The sheep or goats are accompanied by authorized official certification, as described above, that the above conditions have been met.
- The sheep or goats are moved directly from the port of entry as a group to a recognized slaughtering establishment in conveyances sealed at the port of entry with seals of the United States Government, which are broken only at the slaughtering establishment by a USDA representative, and must be slaughtered as a group. The shipment is accompanied by an APHIS Form VS 17–33.

Although there is no naturally occurring BSE infection of sheep and goats, the species can be infected with the BSE agent experimentally. However, in view of the relatively young age of the sheep and goats that would be allowed importation (we would allow importation of sheep and goats only of 12 months of age or less, the industry standard for commercial shipments of such animals), the likelihood that these sheep or goats could provide a source of infection is extremely low.

Sheep or Goats Less Than 12 Months of Age Moved to a Designated Feedlot and Then To Slaughter

We would apply the slaughtering conditions described above to sheep or goats imported for slaughter in the United States after first being contained at a designated feedlot in this country. However, instead of being moved directly from the port of entry to a recognized slaughtering establishment, such animals would be moved to a designated feedlot, and then directly to a recognized slaughtering establishment. For identification purposes, prior to being imported into the United States, each sheep and goat would have to have been tattooed inside one ear with letters identifying the exporting country. Sheep and goats from Canada would have to be tattooed with the letters "CAN."

Therefore, § 93.436(d) would allow the importation of sheep and goats under the following conditions:

- The sheep and goats are not known to have been fed ruminant protein, other than milk protein, during their lifetime and are less than 12 months of age at the time of importation into the United States.
- The inside of one ear on each animal is permanently and legibly tattooed with letters identifying the exporting country.
- The sheep or goats are accompanied by authorized official certification, as described above, that the above conditions have been met.
- The sheep or goats are moved directly from the port of entry as a group to a designated feedlot and the shipment is accompanied by an APHIS Form VS 1–27.
- The sheep or goats are moved directly from the designated feedlot to a recognized slaughtering establishment for slaughter. The shipment is accompanied by APHIS Form VS 1–27.
- The sheep and goats are less than 12 months of age when slaughtered.

Cervids for Immediate Slaughter

Section 93.436, paragraph (e), would allow the importation of cervids under the following conditions:

- The cervids were members of a herd in which surveillance for transmissible spongiform encephalopathies (TSE's) was conducted by appropriate authorities according to national standards or standards of the region itself if the region is a jurisdiction that has effective oversight of normal animal movements into, out of, or within the region and that, in association with national authorities if necessary, has the responsibility for controlling animal disease locally.
- The herd is not known to have been infected with or exposed to a TSE.
- The cervids were born after the implementation of a ban on feeding of ruminant protein to ruminants.
- The cervids were not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The cervids are accompanied by authorized official certification, as described above, that the above conditions have been met.
- The cervids are moved from the port of entry as a group directly to a recognized slaughtering establishment in conveyances sealed at the port of entry with seals of the United States Government, which are broken only at the slaughtering establishment by a USDA representative. The cervids must be slaughtered as a group. The shipment is accompanied by an APHIS Form VS 17–33.

As ruminants, cervids are subject to import restrictions because of BSE. We believe that the above conditions are necessary for the importation of cervids intended for immediate slaughter, because, although there have been no

confirmed cases of BSE in cervids, it is possible that they are susceptible to BSE. To date, there have been no challenge studies for BSE in cervids (*i.e.*, studies in which cervids are intentionally exposed to the BSE agent) to indicate the level of susceptibility of cervids to BSE. Given the stringent controls described above, however, and the fact that there have been no confirmed cases of BSE in cervids, we believe the likelihood BSE would be introduced into the United States through cervid importations is extremely low, and we do not believe that mitigation measures other than those listed above are necessary.

One of the requirements listed above is that the cervids have been members of a herd in which surveillance for TSE's was conducted by appropriate authorities according to national or regional standards. At present, the TSE program for cervids in Canada, the one region we are proposing to classify as BSE-minimal risk at this time, is one that monitors for chronic wasting disease (CWD). However, all sampling done to monitor for CWD would identify animals that might be affected with other TSE's such as BSE.

Ruminant Products From Minimal-Risk Regions

We are proposing to add a new § 94.19 to list those ruminant products that would be allowed importation from a BSE minimal-risk region and to set forth the conditions for such importation.

In evaluating the risk that ruminant products imported into the United States might present, the same factors affecting the BSE risk of the live animals from which the products are derived are applicable. Additionally, other factors must be considered due to the processing the products undergo. Slaughter methods and the removal of risk material from source animals in the exporting region affect the level of risk associated with meat and meat products from those animals, as do intended use and the demonstrated likelihood of the animal product in question to contain the BSE agent.

Similar to the slaughter requirements for ruminants imported live into the United States for immediate slaughter, it would be necessary to require that most ruminant products intended for importation into the United States from a BSE minimal-risk region come from animals from which intestines were removed during processing. In some cases, however, because of other mitigating factors, such as if no natural infection has been observed in the type of animal, we do not believe it would be necessary to require that the intestines have been removed from the animal from which the product is derived.

We believe that the importation of the categories of meat and other edible products from ruminants from BSE minimal-risk regions discussed below would be unlikely to contain the BSE agent provided the following conditions are met, as certified to on an original certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so.

As one of the conditions for bringing the commodity into the United States, we are proposing that the meat and edible products, if arriving at a land border port, arrive only at one of the ports we would list in new § 94.19(k). At this time, the only region that would be listed in § 94.18(a)(3) as a BSE minimal-risk region would be the country of Canada. Because the type of shipments that would require inspection under this proposed rule have not been subject to inspection in recent years when arriving at land border ports from Canada, we believe it is advisable to limit their arrival by land from Canada to those U.S. ports staffed with personnel fully trained in the inspection of such shipments.

We would list the following as designated land border ports in § 94.19(k): Eastport, ID; Houlton, ME; Detroit (Ambassador Bridge), Port Huron, and Sault St. Marie, MI; International Falls, MN; Sweetgrass, MT; Alexandria Bay, Buffalo (Lewiston Bridge and Peace Bridge), and Champlain, NY; Pembina and Portal, ND; Derby Line and Highgate Springs, VT; and Blaine (Pacific Highway and Cargo Ops), Lynden, Oroville, and Sumas (Cargo), WA. If, in the future, we add other countries to the list of BSE minimal-risk regions in § 94.18(a)(3), we would adjust the list of designated ports accordingly.

Fresh (Chilled or Frozen) Meat From Bovines Less Than 30 Months of Age

Section 94.19, paragraph (a), would allow the importation of meat under the following conditions:

- The meat is fresh (chilled or frozen) meat from bovines less than 30 months old at the time of slaughter that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The bovines from which the meat is derived were slaughtered in a slaughtering establishment that slaughters only bovines less than 30 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.
- The intestines of the bovines were removed at slaughter.
- The product qualifies as meat according to the definition of meat set forth in USDA's Food Safety and Inspection Service's (FSIS) regulations at 9 CFR 301.2.
- The shipment is accompanied by authorized official certification, as described above, that the above conditions have been met.

We would require that the commodity meet the definition of "meat" according to the FSIS regulations to ensure that, if imported as ground meat, it has not been combined with meat that might contain high-risk tissues from high-risk animals. Under the FSIS definition in 9 CFR 301.2, to be considered "meat," product that undergoes mechanical separation and meat recovery from the bones of livestock must be processed in such a way that the processing does not crush, grind, or pulverize bones, so that bones emerge comparable to those resulting from hand-deboning and the meat itself meets the criteria of no more than 0.15 percent or 150 mg/100 gm of product for calcium (as a measure of bone solids content) within a tolerance of 0.03 percent or 30 mg. We are proposing to use this standard for the eligibility of meat from bovines (and, as indicated later, for meat from sheep and goats) to ensure that the product contains no mechanically separated meat that might contain high risk-tissues. **(Please note:** Except where the FSIS definition of *meat* is specifically referenced in proposed § 94.19(a)(3) with regard to meat from bovines, and in proposed § 94.19(e)(2) with regard to meat from sheep or goats or other ovines or caprines, the standard dictionary definition of meat is intended throughout this proposed rule.)

To avoid commingling or contamination of meat from bovines under 30 months of age with materials from older bovines, we would require that the slaughtering facility in the region of origin either slaughter only bovines less than 30 months of age or comply with an approved segregation process. Such segregation during

slaughtering could be accomplished, for instance, by slaughtering bovines over 30 months of age only at the end of the day on lines and with equipment dedicated exclusively to slaughtering such older animals.

Fresh (Chilled or Frozen) Whole or Half Carcasses of Bovines Less Than 30 Months of Age

Section 94.19, paragraph (b), would allow the importation of bovine carcasses under the following conditions:

- The products are fresh (chilled or frozen) whole or half carcasses derived from bovines that were less than 30 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The bovines from which the carcasses are derived were slaughtered in a slaughtering establishment that slaughters only bovines less than 30 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling with products not eligible for importation into the United States.
- The intestines of the bovines were removed at slaughter.
- The shipment is accompanied by authorized official certification that the above conditions have been met.

Fresh (Chilled or Frozen) Bovine Liver

Section 94.19, paragraph (c), would allow the importation of fresh (chilled or frozen) bovine liver, provided the product is combined with no other product, is derived from bovines for which no air-injected stunning process was used at slaughter, and is accompanied by authorized official certification that the above conditions have been met. In and of itself, the liver is unlikely to contain infectious levels of the BSE agent, so we are not proposing to require that liver be derived from animals less than 30 months of age or not known to have been fed ruminant protein, other than milk protein, during their lifetime. However, we would prohibit the importation of liver derived from bovines for which an air-injected stunning process was used. The liver, because of its anatomical location and size of its blood vessels, is the organ that could potentially receive emboli or tissue fragments distributed in the animal due to the use of an air-injected stunning process. Because there would be no age limit on the bovines from which the liver is derived, we believe it is necessary to ensure that the liver be free of such potentially high-risk material.

Fresh (Chilled or Frozen) Bovine Tongues

Section 94.19, paragraph (d), would allow the importation of fresh (chilled or frozen) bovine tongues that meet the following conditions:

- The tongues are derived from bovines that were born after the implementation of an effective feed ban.
- The bovines are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The tonsils of the bovines were removed at slaughter.
- The tongues are accompanied by authorized official certification that the above conditions have been met.

The tongue itself is unlikely to contain the BSE agent in animals of any age. However, because the tongue and the tonsils are connected, and the tonsils consist of tissue with demonstrated infectivity, we believe it is necessary to require that the tonsils have been removed from bovines greater than 30 months of age from which tongues for importation are derived. To eliminate the need to determine the exact age of the animals from which tongues are derived, we would require that the tonsils have been removed at slaughter from all bovines from which tongues intended for importation from a BSE minimal-risk region are derived.

Fresh (Chilled or Frozen) Meat of Sheep or Goats or Other Ovines or Caprines

Section 94.19, paragraph (e), would allow the importation of meat under the following conditions:

- The product is fresh (chilled or frozen) meat from sheep or goats or other ovines or caprines less than 12 months of age at the time of slaughter that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The animals from which the meat is derived were slaughtered in a slaughtering establishment that slaughters only sheep and/or goats or other ovines or caprines less than 12 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.
- The product qualifies as meat according to the definition of meat set forth in USDA's Food Safety and Inspection Service's (FSIS) regulations at 9 CFR 301.2.
- The shipment is accompanied by authorized official certification that the above conditions have been met.

Fresh (Chilled or Frozen) Carcasses of Ovines or Caprines

Section 94.19, paragraph (f), would allow the importation of fresh (chilled or frozen) carcasses of ovines and caprines under the following conditions:

- The carcasses are derived from ovines or caprines that were less than 12 months old when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The ovines or caprines from which the carcasses were derived were slaughtered in a slaughtering establishment that slaughters only ovines and/or caprines less than 12 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the carcasses with products not eligible for importation into the United States.
- The carcasses are accompanied by authorized official certification that the above conditions have been met.

Hunter-Harvested Wild Ruminant Products

Section 94.19, paragraph (g), would allow the importation of hunter-harvested wild ruminant products under the following conditions:

- The product is meat or a dressed (eviscerated and the head is removed) carcass of a wild sheep, goat, cervid, or other ruminant;
- The meat or dressed carcass is intended for personal use, and the hunter provides proof to the U.S. Customs and Border Protection official that the animal was a legally harvested wild (not ranched) animal. Such proof will include the hunting license, tag, or equivalent;
- The game and wildlife service of the jurisdiction where the ruminant was harvested has informed the Administrator that the jurisdiction either: (1) Conducts no type of game feeding program, or (2) has complied with, and continues to comply with, the ban on the feeding of ruminant protein to ruminants in the BSE minimal-risk region.

Meat and meat products from wild animals not maintained on ranches or farms are unlikely to have ingested contaminated commercial feed and are unlikely to have infectious levels of the BSE agent. Also, the nature of hunter-harvested ruminant products to be used

for personal use makes it highly unlikely that the product will enter the commercial food chain for animals. (In § 94.0, we would add a definition of *personal use* to mean only for personal consumption or display and not distributed further or sold.) If the game and wildlife service of the jurisdiction where the ruminant was harvested has not informed the Administrator either that the jurisdiction conducts no game feeding program or has complied with, and continues to comply with, the feed ban, we would direct U.S. inspectors at the designated ports of arrival not to allow such hunter-harvested ruminant products from the jurisdiction to be imported into the United States.

Fresh (Chilled or Frozen) Meat of Cervids Either Farm-Raised or Harvested on a Game Farm or Similar Facility

Section 94.19, paragraph (h), would allow the importation of meat and meat products under the following conditions:

- The product is fresh (chilled or frozen) meat derived from cervids that were born after an effective feed ban was implemented, that were not known to have been fed ruminant protein, other than milk protein, during their lifetime, and that were members of a herd not known to be infected with or exposed to a transmissible spongiform encephalopathy.
- If the product is ground meat or sausage, it was derived either from all cervine meat or from cervine meat mixed with nonruminant meat.
- The shipment is accompanied by authorized official certification that the above conditions have been met.

No natural infection of BSE has been documented in cervids, and we believe there is a very low risk that any tissue in cervids is likely to contain the BSE agent. Therefore, we believe it is unnecessary to prohibit the importation of ground meat or sausage that is exclusively cervid meat or cervid meat and nonruminant meat. However, because it has not been proven that cervids are not susceptible to BSE, we believe it is necessary to require that the cervid meat and meat products be derived from cervids that were members of a herd not known to have been infected with or exposed to a transmissible spongiform encephalopathy.

Fresh (Chilled or Frozen) Meat From Wild-Harvested Caribou, Musk Ox, or Other Cervids

Section 94.19, paragraph (i), would allow the importation of meat under the following conditions:

- The meat is from wild caribou, musk ox, or other cervids harvested within a jurisdiction specified by the Administrator for which the game and wildlife service has informed the Administrator that the jurisdiction either: (1) Conducts no type of game feeding program, or (2) has complied with, and continues to comply with, the ban on the feeding of ruminant protein to ruminants in the BSE minimal-risk region.
- The cervids from which the meat is derived were either slaughtered in a slaughtering establishment that slaughters only cervids eligible for entry into the United States or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.
- The shipment is accompanied by authorized official certification that the above conditions have been met.

This meat differs from the meat described above under the heading "Hunter-harvested wild ruminant products" in that, although it is hunter-harvested, it is done so on a larger scale for commercial sale.

Gelatin

Section 94.19, paragraph (j), would allow the importation of gelatin from bones of bovines that were less than 30 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, provided the shipment is accompanied by authorized official certification that these conditions have been met.

Importation of Certain Tallow and Offal

Section 95.4 of the regulations currently restricts the importation of animal protein, tankage, fat, glands, tallow other than tallow derivatives, and serum from regions where BSE is known to exist or that present an undue risk of BSE. Of these products, we believe that certain tallow and offal could be imported from BSE minimal-risk regions under certain conditions with little likelihood of containing infectious levels of the BSE agent, and are proposing to amend § 95.4 to allow the importation of such materials. We do not have evidence at this time that the other products prohibited under § 95.4 could be imported with little likelihood of containing infectious levels of the BSE agent.

As one of the conditions for importation, the tallow and offal, if arriving at a U.S. land border port, would have to arrive at one of the ports we would list in new § 94.19(k).

Tallow

In the case of tallow, we would require that it contain less than 0.15 percent protein and be obtained from bovines less than 30 months of age when slaughtered. This product would be considered low risk because it is primarily lipid material with a minimal cellular component. When it is derived from low-risk bovines and the level of protein is low, the material would be unlikely to contain prion protein.

Section 95.4, paragraph (f), would allow the importation of tallow under the following conditions:

- The tallow is composed of less than 0.15 percent protein.
- The tallow was derived from animals that were less than 30 months of age when slaughtered, that were born after the region of origin implemented an effective ban on the feeding of ruminant protein to ruminants, and that were not known to have been ruminant protein, other than milk protein, during their lifetime.
- The tallow is not derived from an animal that died otherwise than by slaughter.
- The intestines were removed from each animal at slaughter.
- The shipment of tallow to the United States is accompanied by authorized official certification that the above conditions have been met.

Cervine Offal

In the case of offal, we would require that it be derived from cervids born after the implementation of an effective feed ban that were not known to have been fed ruminant protein, other than milk protein. Because the offal would be derived from low-risk animals, we would consider the product to be unlikely to contain the BSE agent. We would limit the importation of offal to cervine offal, because bovine offal could contain the distal ileum, which is a tissue with confirmed infectivity in BSE-infected bovines.

Section 95.4, paragraph (g), would allow the importation of offal from cervids under the following conditions:

- The offal was derived from cervids that were born after the feed ban, that were not known to have been fed ruminant protein, other than milk protein, during their lifetime, and that were members of a herd not known to be infected with or exposed to a transmissible spongiform encephalopathy.
- The shipment of offal to the United States is accompanied by authorized

official certification that the above conditions have been met.

Additionally, because offal can encompass a variety of materials, for clarification we would add a definition of offal to § 95.1 to mean the parts of a butchered animal that are removed in dressing, consisting largely of the viscera and the trimmings, which may include, but are not limited to, brains, thymus, pancreas, liver, heart, and kidney.

APHIS Inspection of Processing and Handling Facilities; Certification of Compliance

Although § 95.4 restricts the importation of animal protein, tankage, fat, glands, tallow other than tallow derivatives, and serum from regions where BSE is known to exist or that present an undue risk of BSE (as listed in current § 94.18(a)), paragraph (c) of § 95.4 exempts certain materials from the restrictions, under certain conditions, provided the material is derived from a nonruminant species, or from a ruminant species if the ruminants have never been in a region listed in § 94.18(a). One of the conditions for such importation is that all steps of processing and storing the material be carried out in a facility that has not been used for the processing or storage of any materials derived from ruminants that have been in any region listed in § 94.18(a). A further requirement is that, if the facility processes or handles any material derived from mammals, the facility must have entered into a cooperative service agreement with APHIS to pay for the costs of an APHIS veterinarian to make annual inspections of the facility.

Because we believe the regions we are proposing to include in § 94.18(a)(3) of this proposal present a minimal risk for BSE, we believe that, in lieu of annual APHIS inspections of the facility, such inspections could be carried out by the government agency responsible for animal health in the region, although APHIS would reserve the right to inspect as deemed necessary. Therefore, we are proposing to amend § 95.4(c)(4) to exclude facilities in BSE minimal-risk regions from the requirement for a cooperative service agreement and to require that annual inspections of the facility be carried out by a representative of the government agency responsible for animal health in the region. We would, however, still apply to BSE minimal-risk regions the provisions of § 95.4(c)(5), which require the facility to allow periodic inspections by APHIS.

Additionally, we are proposing to amend § 95.4(c)(6), which currently specifies that each shipment imported into the United States in accordance with § 95.4(c) be accompanied by an original certificate signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the region of export certifying that the conditions of that section have been met. Because of the reduced risk of such exports from regions we would consider minimal risk, we are proposing to provide in § 95.4(c)(6) that, for shipments of animal feed, the necessary certification may be signed by a person authorized to issue such certificates by the veterinary services of the national government of the region of origin.

Definitions

In addition to adding definitions of *as a group, designated feedlot, bovine spongiform encephalopathy (BSE) minimal-risk region, offal,* and *personal use* to the regulations, as discussed above, we are proposing to define in § 93.400 the term *USDA representative* to mean a veterinarian or other individual employed by the United States Department of Agriculture who is authorized to perform the services required by part 93.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

Under the Animal Health Protection Act of 2002 (7 U.S.C. 8301 *et seq.*) the Secretary of Agriculture is authorized to promulgate regulations to prevent the introduction into the United States or dissemination of any pest or disease of livestock.

On May 20, 2003, the Canadian Food Inspection Agency reported a case of BSE in a beef cow in northern Alberta. To prevent the introduction of this disease into the United States, APHIS issued an interim rule to classify Canada as a region where BSE exists, thereby prohibiting the importation of ruminants and most ruminant products from Canada, effective May 20, 2003.

This proposed rule would amend the regulations by establishing a category of regions that present a minimal risk of introducing BSE into the United States. The rule would set forth factors considered for placing a region in this category, and risk mitigations that would be required for the importation of certain ruminants and ruminant products from such regions. Although the proposed rule would list Canada as the only BSE minimal-risk region at this time, APHIS would evaluate requests and supporting information submitted by other regions for inclusion in this category.

In accordance with Executive Order 12866 and the Regulatory Flexibility Act, we assessed the potential economic costs and benefits of this rule and potential effects on small entities. Although not addressed in the analysis, Canadian producers/suppliers of ruminants and ruminant products would benefit from the resumption of exports to the United States.

Below is a summary of our economic analysis. A copy of the full economic analysis is available for review in our reading room (see the **ADDRESSES** section at the beginning of this document). You may also view the economic analysis on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov.* At the APHIS Web site, click on the "Hot Issues" button. On the next screen, click on the listing for "Bovine Spongiform Encephalopathy (BSE)." On the next screen, click on the listing for "Economic Analysis, Proposed Rule, Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities (APHIS Docket No. 03–080–1)." We do not have enough data for a comprehensive analysis of the potential economic effect of this proposed rule on small entities. Therefore, in accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis for this proposed rule. We are inviting comments about this proposed rule as it relates to small entities. In particular, we are interested in determining the number and kind of small entities that would incur benefits or costs from the implementation of this proposed rule and the economic effect of those benefits or costs.

Because Canada is the only region we are proposing to include in the BSE minimal-risk category at this time, ruminant and ruminant product imports from Canada that would be reestablished under the proposed rule are the focus of our analysis. However, this minimal-risk category is not limited to Canada and could include other regions in the future. The analysis also considers effects of the rule for U.S. ruminant and ruminant product exports should other countries not consider our minimal-risk requirements sufficient to safeguard against BSE introduction into the United States and/or do not accept our listing of Canada as a region of minimal risk.

The commodities that would be allowed to enter under the proposed rule are:

- Cattle less than 30 months of age, sheep and goats less than 12 months of age, and cervids of any age, imported in all cases for immediate slaughter;
- Cattle less than 30 months of age and sheep and goats less than 12 months of age imported for feeding at a designated feedlot (for slaughter at less than 30 months and 12 months of age, respectively);
- Meat from cattle, sheep, and goats that have been slaughtered within these age restrictions;
- Meat of cervids either farm-raised or harvested on a game farm or similar facility;
- Meat from wild-harvested caribou, musk ox, or other cervids that has been commercially processed;
- Certain hunter-harvested wild ruminant products for personal use; and
- Certain other products and byproducts, including bovine livers and tongues, gelatin, tallow, and cervid offal.

With respect to Canada, slaughter cattle, feeder cattle, and beef would be the main commodities affected by resumption of ruminant and ruminant product imports. The additional supplies would cause prices to fall. Welfare gains for consumers and losses for producers/suppliers are measured, and net benefits and losses estimated. Since May of this year, U.S. producers/suppliers of ruminants and ruminant products have benefited from high price levels at least partly attributable to the ban on imports from Canada. Estimated price declines for producers/suppliers and consumers/buyers of slaughter cattle, feeder cattle, and beef largely reflect a return to the more normal market conditions that prevailed before Canada's BSE discovery.

Expected effects due to reestablished slaughter cattle and feeder cattle imports from Canada are shown in table 1. (The model and parameters used are explained in the body of the economic analysis.) The estimated effects are near-term, and would occur during the first year or so following the resumption of imports. In the longer term, production and marketing adjustments in response to changed market conditions would create new price-quantity equilibriums.

TABLE 1.—ECONOMIC EFFECTS OF REESTABLISHED SLAUGHTER CATTLE AND FEEDER CATTLE IMPORTS FROM CANADA

	Slaughter cattle	Feeder cattle
Assumed reestablished slaughter and feeder cattle imports from Canada (head)	840,800	504,500
Change in numbers slaughtered and fed (head)	366,350	221,318
Change in numbers supplied by U.S. entities (head)	(474,450)	(283,182)
Change in the prices of slaughter and feeder cattle (dollars per 100 pounds)	($1.30)	($0.72)
Change in consumer surplus	$455,317,000	$188,220,000
Change in producer surplus	($448,744,000)	($182,053,000)
Annual net benefit	$6,573,000	$6,167,000

Reestablished slaughter cattle imports from Canada of 840,000 head would result in a price decline of $1.30 per 100 pounds. This price decline would be accompanied by an increase of about 366,350 head in the number of cattle slaughtered, and a decrease of 474,450 head in the number of slaughter cattle supplied by U.S. entities. These changes translate into an increase in consumer surplus of $455.3 million for buyers of slaughter cattle, and a decrease in producer surplus of $448.7 million for sellers of slaughter cattle, for an annual net benefit of $6.6 million.

Whether a portion of this benefit would be realized by beef consumers would depend upon wholesale and retail margins and elasticities of demand. The price decline would reduce incomes of domestic suppliers who would be competing with slaughter cattle imports from Canada. The estimated price change is small, falling within expected variations of recent USDA price projections. A price decrease of $1.30 per 100 pounds would represent a decline of 1.7 percent and would not significantly affect buyers or sellers of slaughter cattle.

Reestablished feeder cattle imports from Canada totaling 504,500 head would result in a price decline of 72 cents per 100 pounds. This fall in price would be accompanied by an increase of 221,318 head in the number of cattle fed, and a decrease of 283,182 head in the number of cattle supplied to feedlots by U.S. entities. Consumer surplus would rise by $188.2 million for buyers of feeder cattle, and producer surplus would fall by $182 million for sellers of feeder cattle, for an annual net benefit of about $6.2 million.

A price decline resulting from reestablished feeder cattle imports from Canada would benefit the receiving feedlots. The decline would also reduce incomes for domestic suppliers, such as stocker operations, in competition with importers of feeder cattle from Canada. The estimated effects are small. A price decrease of 72 cents per 100 pounds would represent a decline of 0.9 percent and would not result in significant gains or losses for the affected entities.

Beef is modeled as a single aggregate commodity, but two analyses are performed. Boneless beef and certain other ruminant products are allowed to enter the United States from Canada under permit. We do not know whether quantities of boneless beef that enter under permit will reach levels that prevailed prior to the ban. This uncertainty is acknowledged by using two different import levels. The first analysis assumes that boneless beef imports from Canada under permit will reach 2002 levels; the effect of the proposed rule with respect to beef would be in reestablishing beef with bone and whole/half carcass imports. The second analysis assumes that no boneless beef is imported under permit, and all reestablished beef imports from Canada would be attributable to the proposed rule. The two analyses are hypothetical extremes that provide a lower bound and an upper bound of possible effects. Effects for two price levels of beef, $3.00 and $3.50 per pound, are estimated, as shown in table 2.

TABLE 2.—ECONOMIC EFFECTS OF REESTABLISHED BEEF IMPORTS FROM CANADA, FOR HYPOTHETICAL LOWER AND UPPER BOUNDS OF POSSIBLE EFFECTS OF THE PROPOSED RULE

	Only reestablished beef with bone and whole/half carcass imports from Canada assumed attributable to the proposed rule		All reestablished beef imports from Canada assumed attributable to the proposed rule	
	$3.00 per pound beef	$3.50 per pound beef	$3.00 per pound beef	$3.50 per pound beef
Assumed beef imports from Canada (tons)	84,000	84,000	382,000	382,000
Change in U.S. consumption (tons)	40,324	40,324	183,378	183,378
Change in U.S. production (tons)	(43,676)	(43,676)	(198,622)	(198,622)
Change in the price of beef (per pound)	(1.1 cents)	(1.3 cents)	(5.2 cents)	(6.1 cents)
Change in consumer surplus	$313,260,000	$365,455,000	$1,416,390,000	$1,652,383,000
Change in producer surplus	($289,425,000)	($337,648,000)	($1,325,068,000)	($1,545,845,000)
Annual net benefit	$23,835,000	$27,807,000	$91,322,000	$106,538,000

For beef prices of $3.00 and $3.50 per pound, respectively, annual net benefits of established beef imports would be $23.8 million and $27.8 million (only beef with bone and whole/half carcass imports assumed to be reestablished due to the proposed rule), and $91.3 million and $106.5 million (all beef imports assumed to be reestablished due to the proposed rule). As with reestablished imports of slaughter and feeder cattle, expected price declines due to reestablished beef imports from Canada would not be of a magnitude to significantly affect the economic welfare of producers or consumers. In the first case, price declines of 1.1 cents and 1.3 cents per pound are estimated for assumed beef prices of $3.00 and $3.50 per pound, respectively. In the second case, price declines of 5.2 cents and 6.1 cents per pound are estimated. Even in the latter analysis (all reestablished beef imports from Canada attributable to the proposed rule), the price declines represent less than a 2 percent fall in price.

Other, more minor commodities that would be allowed entry under the proposed rule and for which we have trade data are sheep, goats, and farmed cervids; meat from these ruminants; and bovine tongues and livers. In all cases, reestablished imports from Canada would not significantly affect the U.S. supply of these commodities or the welfare of U.S. entities.

The United States prohibits ruminant imports from BSE-affected regions. Under the proposed rule, the United States would recognize Canada as a minimal-risk region for BSE, under which ruminant imports could resume. U.S. ruminant and ruminant product exports would be placed in jeopardy if importing countries do not agree that the factors the United States would consider justify the categorization of a region as one of minimal risk, and do not agree that the proposed age restrictions and other measures provide an adequate safeguard against the risk of BSE introduction from such a region.

We therefore analyze the economic effects that would occur if the United States would lose major export markets due to this proposed rule and its inclusion of Canada as a minimal-risk region.

Because U.S. ruminant and ruminant product exports to Canada and Mexico would not be jeopardized by this proposed rule, exports to these two countries are excluded from the analysis. Since nearly all U.S. cattle exports are to Canada and Mexico, we can also limit the analysis to possible effects for beef exports.

Canada and Mexico together imported about 36 percent of U.S. beef exports in 2002. Removing these exports from consideration leaves about 64 percent of U.S. beef exports that could be affected by the proposed rule. About 56 percent of U.S. beef exports (over 87 percent, excluding shipments to Canada and Mexico) were sold to Japan and Korea. Given the predominance of these two countries among importers of U.S. beef, the analysis is performed for two levels of export reduction: 32 percent of 2002 exports, or 263,360 tons (loss of one-half of export markets other than Canada and Mexico), and 64 percent, or 546,720 tons (loss of all export markets other than Canada and Mexico). For each of these assumed levels of export reduction, impacts are estimated using the same beef prices, $3.00 and $3.50 per pound. The results of the analysis are shown in table 3.

TABLE 3.—ECONOMIC EFFECTS OF THE LOSS OF U.S. BEEF EXPORT MARKETS, ASSUMING EXPORT REDUCTIONS OF 32 PERCENT AND 64 PERCENT

[Quantities equivalent to one-half and all U.S. beef exports when exports to Canada and Mexico are excluded]

	Loss of export markets equivalent to 32 percent of 2002 beef exports		Loss of export markets equivalent to 64 percent of 2002 beef exports	
	$3.00 per pound beef	$3.50 per pound beef	$3.00 per pound beef	$3.50 per pound beef
Assumed reduction in beef exports (tons)	263,360	263,360	546,720	546,720
Change in U.S. consumption (tons)	116,483	116,483	232,967	232,967
Change in U.S. production (tons)	(146,877)	(146,877)	(293,753)	(293,753)
Change in the price of beef (cents per pound)	(3.6 cents)	(4.2 cents)	(7.2 cents)	(8.4 cents)
Change in consumer surplus	$910,983,000	$1,062,767,000	$1,831,174,000	$2,136,278,000
Change in producer surplus	($965,636,000)	($1,126,526,000)	($1,919,660,000)	($2,239,507,000)
Annual net benefit	($54,653,000)	($63,759,000)	($88,486,000)	($103,229,000)

Loss of one-half of U.S. beef export markets other than Canada and Mexico and redirection of the beef to the U.S. market would result in annual net welfare losses of about $54.7 million and $63.8 million, for beef prices of $3.00 and $3.50 per pound, respectively. The associated declines in price would be 3.6 cents and 4.2 cents per pound. The effects if all U.S. beef export markets other than Canada and Mexico were to close would be annual net welfare losses of about $88.5 million and $103.2 million for the two beef price levels, with decreases in price of 7.2 cents and 8.4 cents per pound. As explained, these effects would occur only if the proposed rule is adopted as final and the countries to which the United States exports beef decided to refuse its entry as a result.

The main industries that would be affected by the proposed rule, such as livestock producers, slaughtering establishments, and meat processors, are composed predominantly of small entities. As indicated above, since May of this year, U.S. producers/suppliers of ruminants and ruminant products have benefited from high price levels at least partly attributable to the ban on imports from Canada. By the same token, buyers of slaughter cattle, feeder cattle, and beef would benefit from price declines (slaughter cattle, 1.7 percent; feeder cattle, 0.9 percent; and beef, less than 2 percent) resulting from the reestablishment of these imports.

Effects from the possible loss of U.S. export markets and subsequent industry contractions, if this proposed rule is adopted as final and other countries were to refuse entry of our beef as a result, would harm small as well as large entities. This outcome could occur, even though BSE has never been discovered in the United States, if, as described above, countries importing U.S. beef do not agree that the factors the United States would consider justify the categorization of a region as one of minimal risk, and do not agree that the proposed age restrictions and other measures provide an adequate safeguard against the risk of BSE introduction from such a region.

Alternatives to the proposed rule would be to (1) leave the regulations unchanged—that is, continue to prohibit entry of ruminants and most ruminant products from regions of minimal BSE risk (other than products allowed entry under permit), or (2) allow the commodities to enter from such regions without the age restrictions or other measures set forth in the proposed rule. Because Canada is the only country we are proposing to list as a BSE minimal-risk region at this time, the alternatives are discussed in terms of Canada.

By maintaining current import restrictions, estimated benefits of reestablishing slaughter cattle, feeder cattle, and beef imports from Canada would not be realized. Continuation of the status quo would also eliminate any possibility of adverse effects for U.S. exports.

Concerning the second alternative, the proposed age requirements and other measures are based on the known epidemiology of BSE. Without these mitigations, we believe importation of ruminants and ruminant products (other than those allowed entry by permit) would expose the United States to greater risk of BSE introduction.

A BSE discovery in the United States would have economic consequences similar to those that have occurred in Canada and elsewhere. Losses would take the form of lowered demand, closed export markets, animal depopulations, and increased government expenditures for disease management and compensation for depopulated livestock. Tens of thousands of jobs with total earnings in the hundreds of millions of dollars could be threatened by the loss of export markets due to a discovery of BSE.

Because BSE has been linked to variant Creutzfield-Jakob disease, one of the most significant impacts of a BSE occurrence in the United States would be the potential loss of consumer confidence in the safety of the U.S. beef supply. An incidence of BSE could result in a downward shift in demand for beef, leading to lowered prices and production.

APHIS acknowledges a theoretical increased risk of BSE introduction into the United States because of this rule. However, we conclude in the risk analysis used as a basis for this rule that, with the proposed mitigation measures, this risk is extremely small. If an introduction occurred, few, if any, additional animals would be infected. It is highly unlikely that such an introduction would pose a major animal health or public health threat in the United States; regulations and practices in the United States are robust and would militate against human exposure or disease spread.

The proposed rule is considered preferable to either continuing to prohibit the entry of ruminants and certain ruminant products from a BSE minimal-risk region or allowing their entry unconditionally. We believe the factors considered in listing a region as one of minimal risk and the mitigations required for the entry of ruminants and ruminant products would make the likelihood of the introduction of even one animal or product containing infectious levels of the BSE agent extremely small. We also believe that listing Canada as a BSE minimal-risk region, together with the risk-mitigation measures that would be required, is a balanced, science-based response to Canada's request that ruminants and certain ruminant product imports by the United States from Canada be allowed to resume.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

National Environmental Policy Act

We have prepared an environmental assessment regarding the potential impact on the quality of the human environment due to the importation of ruminants and ruminant products and byproducts from Canada under the conditions specified in this proposed rule. APHIS' review and analysis of the potential environmental impacts associated with these proposed importations are documented in an environmental assessment titled "Proposed Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products from Canada into the United States, Environmental Assessment (October 2003)." We are making this environmental assessment available to the public for review and comment. We will consider all comments that we receive on or before the date listed under the heading **DATES** at the beginning of this notice.

Copies of the environmental assessment are available for public inspection in our reading room (information on the location and hours of the reading room is provided under the heading **ADDRESSES** at the beginning of this proposed rule). In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT.** The environmental assessment may also be viewed on the Internet at *http://www.aphis.usda.gov/ppd/es/vsdocs.html.*

The environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the

Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 03–080–1. Please send a copy of your comments to: (1) Docket No. 03–080–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would recognize a category of regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products, and would add Canada to this category. The proposed rule would also allow the importation of certain live ruminants and ruminant products from such BSE minimal-risk regions under certain conditions.

Accomplishing this would require the use of several information collection activities, including the completion of certification statements for the importation of both ruminants and ruminant-derived products by the national veterinary authority of the region of origin, permits for the movement of restricted animals, forms associated with the importation of animals for immediate slaughter, the placing of seals on certain conveyances, and the tattooing of letters on certain livestock.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 2 hours per response.

Respondents: Canadian veterinary authorities, herd owners, and exporters of ruminants and ruminant-derived products; slaughter plant and feedlot personnel in the United States, accredited veterinarians, and State veterinary authorities.

Estimated annual number of respondents: 6,000.

Estimated annual number of responses per respondent: 20.

Estimated annual number of responses: 120,000.

Estimated total annual burden on respondents: 240,000 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

Accordingly, we propose to amend 9 CFR parts 93, 94, and 95 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

1. The authority citation for part 93 would continue to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. Section 93.400 would be amended by adding definitions of *as a group, designated feedlot,* and *USDA representative,* in alphabetical order, to read as follows:

§ 93.400 Definitions.

* * * * *

As a group. Collectively, in such a manner that the identity of the animals as a unique group is maintained.

* * * * *

Designated feedlot. A feedlot indicated on the declaration required under § 93.407 as the destination of the ruminants imported into the United States.

* * * * *

USDA representative. A veterinarian or other individual employed by the United States Department of Agriculture who is authorized to perform the services required by this part.

* * * * *

3. A new § 93.436 would be added to subpart D to read as follows:

§ 93.436 Ruminants from regions of minimal risk for BSE.

The importation of ruminants from regions listed in § 94.18(a)(3) of this subchapter is prohibited, unless the conditions of this section and any other applicable conditions of this part are met. Once the ruminants are imported, if they do not meet the conditions of this section, they must be disposed of as the Administrator may direct.

(a) *Bovines for immediate slaughter.* Bovines from a region listed in § 94.18(a)(3) of this subchapter may be imported for immediate slaughter under the following conditions:

(1) The bovines must be less than 30 months of age when imported into the United States;

(2) The bovines must not have been known to have been fed ruminant protein, other than milk protein, during their lifetime;

(3) The bovines must be accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so, that states that the conditions of paragraphs (a)(1) and (a)(2) of this section have been met;

(4) The bovines must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and must be moved directly as a group from the port of entry to a recognized slaughtering establishment in conveyances that must be sealed with seals of the U.S. Government at the port of entry. The seals may be broken only at the recognized slaughtering establishment by a USDA representative;

(5) The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33;

(6) At the recognized slaughtering establishment, the animals must be slaughtered as a group and each animal's intestines must be removed; and

(7) The intestines removed from the animals must be disposed of in a manner approved by the Administrator.

(b) *Bovines for feeding.* Bovines from a region listed in § 94.18(a)(3) of this subchapter may be imported under the following conditions:

(1) The bovines must be less than 30 months of age when imported into the United States;

(2) The bovines must not have been known to have been fed ruminant protein, other than milk protein, during their lifetime;

(3) The inside of one ear on each animal must be permanently and legibly tattooed with letters identifying the exporting country. Animals exported from Canada must be tattooed with the letters "CAN";

(4) The bovines must be accompanied by a certificate issued in accordance with § 93.405(a) that states, in addition to the statements required by § 94.405(a), that the conditions of paragraphs (b)(1) through (b)(3) of this section have been met;

(5) The bovines must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and must be moved directly from the port of entry as a group to the designated feedlot;

(6) The shipment must be accompanied from the port of entry to the designated feedlot by APHIS Form VS 1–27;

(7) The bovines must be moved directly from the designated feedlot to a recognized slaughtering establishment for slaughter;

(8) The shipment must be accompanied from the designated feedlot to the recognized slaughtering establishment by APHIS Form VS 1–27;

(9) The bovines must be less than 30 months of age when slaughtered;

(10) At the recognized slaughtering establishment, each animal's intestines must be removed; and

(11) The intestines removed from the animals must be disposed of in a manner approved by the Administrator.

(c) *Sheep or goats for immediate slaughter.* Sheep and goats from a region listed in § 94.18(a)(3) of this subchapter may be imported for immediate slaughter under the following conditions:

(1) The sheep or goats must be less than 12 months of age when imported into the United States;

(2) The sheep or goats must not have been known to have been fed ruminant protein, other than milk protein, during their lifetime;

(3) The sheep or goats must be accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so, that states that the conditions of paragraphs (c)(1) and (c)(2) of this section have been met;

(4) The sheep or goats must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and must be moved directly as a group from the port of entry to a recognized slaughtering establishment for slaughter as a group in conveyances that must be sealed with seals of the U.S. Government at the port of entry. The seals may be broken only at the recognized slaughtering establishment by a USDA representative; and

(5) The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33.

(d) *Sheep or goats for feeding.* Sheep and goats from a region listed in § 94.18(a)(3) of this subchapter may be imported under the following conditions:

(1) The sheep or goats must be less than 12 months of age when imported into the United States;

(2) The sheep or goats must not have been known to have been fed ruminant protein, other than milk protein, during their lifetime;

(3) The inside of one ear on each animal must be permanently and legibly tattooed with letters identifying the exporting country. Animals from Canada must be tattooed with the letters "CAN";

(4) The sheep or goats must be accompanied by a certificate issued in accordance with § 93.405(a) that states, in addition to the statements required by § 94.405(a), that the conditions of paragraphs (d)(1) through (d)(3) of this section have been met;

(5) The sheep or goats may be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and must be moved directly as a group from the port of entry to a designated feedlot;

(6) The shipment must be accompanied from the port of entry to the designated feedlot by APHIS Form VS 1–27;

(7) The sheep or goats must be moved directly from the designated feedlot to a recognized slaughtering establishment for slaughter;

(8) The shipment must be accompanied from the designated feedlot to the recognized slaughtering establishment by APHIS Form VS 1–27; and

(9) The sheep and goats must be less than 12 months of age when slaughtered.

(e) *Cervids for immediate slaughter.* Cervids from a region listed in § 94.18(a)(3) of this subchapter may be imported for immediate slaughter under the following conditions:

(1) The cervids must have been members of a herd in which surveillance for transmissible spongiform encephalopathies was conducted by appropriate authorities according to national standards or standards of the region itself if the region is a jurisdiction that has effective oversight of normal animal movements into, out of, or within the region and that, in association with national authorities if necessary, has the

responsibility for controlling animal disease locally;

(2) The cervids must have been members of a herd not known to be infected with or exposed to a transmissible spongiform encephalopathy;

(3) The cervids must have been born after a ban on the feeding of ruminant protein to ruminants was implemented;

(4) The cervids must not have been known to have been fed ruminant protein, other than milk protein, during their lifetime;

(5) The cervids must be accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so, that states the conditions of paragraphs (e)(1) through (e)(4) of this section have been met;

(6) The cervids must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and must be moved directly from the port of entry as a group to a recognized slaughtering establishment for slaughter as a group in conveyances that must be sealed with seals of the U.S. Government at the port of entry. The seals may be broken only at the recognized slaughtering establishment by a USDA representative; and

(7) The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

4. The authority citation for part 94 would continue to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

5. Section 94.0 would be amended by adding new definitions of *bovine spongiform encephalopathy (BSE) minimal-risk region*, and *personal use*, in alphabetical order, to read as follows:

§ 94.0 Definitions.

* * * * *

Bovine spongiform encephalopathy (BSE) minimal-risk region. A region that:

(1) Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

(i) Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;

(ii) Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE; and

(iii) A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

(2) In regions where BSE was detected, conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

(3) In regions where BSE was detected, took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

* * * * *

Personal use. Only for personal consumption or display and not distributed further or sold.

* * * * *

§ 94.1 [Amended]

6. In § 94.1, paragraph (b)(4) and the introductory text to paragraph (d) would be amended by removing the reference to "§ 94.21" each time it appears and replacing it with a reference to "§ 94.22".

7. Section 94.18 would be amended as follows:

a. Paragraph (a)(3) would be redesignated as paragraph (a)(4) and revised to read as set forth below.

b. A new paragraph (a)(3) would be added, and paragraph (b) and the introductory text of paragraph (c) would be revised, to read as set forth below.

§ 94.18 Restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy.

(a) * * *

(3) The following are minimal-risk regions with regard to bovine spongiform encephalopathy: Canada.

(4) A region may request at any time that the Administrator consider its removal from a list in paragraphs (a)(1) or (a)(2) or this section, or its addition to or removal from the list in paragraph (a)(3) of this section, by following the procedures in part 92 of this subchapter.

(b) Except as provided in paragraph (d) of this section or in § 94.19, the importation of fresh (chilled or frozen) meat, meat products, and edible products other than meat (except for gelatin as provided in paragraph (c) of this section, milk, and milk products), from ruminants that have been in any of the regions listed in paragraph (a) of this section is prohibited.

(c) *Gelatin.* The importation of gelatin derived from ruminants that have been in any region listed in paragraph (a) of this section is prohibited unless the following conditions, or the conditions of § 94.19(j), have been met:

* * * * *

8. Sections 94.19 through 94.24 would be redesignated as §§ 94.20 through 94.25, respectively.

9. A new § 94.19 would be added to read as follows:

§ 94.19 Restrictions on importation from BSE minimal-risk regions of meat and edible products from ruminants.

Except as provided in § 94.18 and this section, the importation of fresh (chilled or frozen) meat, meat products, and edible products other than meat (excluding gelatin, milk, and milk products), from ruminants that have been in any of the regions listed in § 94.18(a)(3) is prohibited. The commodities listed in paragraphs (a) through (j) of this section may be imported from a region listed in § 94.18(a)(3) if the conditions listed are met and if, except for the commodities described in paragraph (g), the commodities are accompanied by an original certificate of such compliance issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so.

(a) *Fresh (chilled or frozen) meat from bovines less than 30 months of age.* The

meat is derived from bovines that were less than 30 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and meets the following conditions:

(1) The bovines from which the meat is derived were slaughtered at a facility that either slaughters only bovines less than 30 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.

(2) The intestines of the bovines were removed at slaughter; and

(3) The product qualifies as *meat* under the definition of *meat* in USDA's Food Safety and Inspection Service's regulations at 9 CFR 301.2.

(b) *Fresh (chilled or frozen) whole or half carcasses of bovines less than 30 months of age.* The carcasses are derived from bovines that meet the following conditions:

(1) The bovines were less than 30 months of age when slaughtered;

(2) The bovines are not known to have been fed ruminant protein, other than milk protein, during their lifetime;

(3) The intestines of the bovines were removed at slaughter; and

(4) The bovines were slaughtered at a facility that either slaughters only bovines less than 30 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling with products not eligible for importation into the United States.

(c) *Fresh (chilled or frozen) bovine liver.* The commodity is liver containing no other product and is derived from bovines for which an air-injected stunning process was not used at slaughter.

(d) *Fresh (chilled or frozen) bovine tongues.* The tongues are derived from bovines that were born after the region implemented an effective ban on the feeding of ruminant protein to ruminants, that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and from which the tonsils of each animal were removed at slaughter.

(e) *Fresh (chilled or frozen) meat of sheep or goats or other ovines or caprines.* The meat is from sheep or goats or other ovines or caprines that were less than 12 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and meets the following conditions:

(1) The meat is derived from sheep or goats or other ovines or caprines that were slaughtered at a facility that either slaughters only sheep and/or goats or other ovines and caprines less than 12 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States; and

(2) The product qualifies as meat under the definition of *meat* in USDA's Food Safety and Inspection Service's regulations at 9 CFR 301.2.

(f) *Fresh (chilled or frozen) carcasses of ovines and caprines.* The carcasses are derived from ovines or caprines that were less than 12 months of age when slaughtered, that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and that were slaughtered at a facility that either slaughters only ovines and/or caprines less than 12 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the carcasses with products not eligible for importation into the United States.

(g) *Fresh (chilled or frozen) meat or dressed carcasses of hunter-harvested wild sheep, goats, cervids, or other ruminants.* The meat or dressed carcass (eviscerated and the head is removed) is derived from a wild sheep, goat, cervid, or other ruminant and meets the following conditions:

(1) The meat or dressed carcass is intended for personal use and is derived from an animal that has been legally harvested in the wild, as verified by proof such as a hunting license, tag, or the equivalent that the hunter must show to the United States Customs and Border Protection official; and

(2) The animals from which the meat is derived were harvested within a jurisdiction specified by the Administrator for which the game and wildlife service of the jurisdiction has informed the Administrator either that the jurisdiction conducts no type of game feeding program, or has complied with, and continues to comply with, the ban on the feeding of ruminant protein to ruminants in the BSE minimal-risk region.

(h) *Fresh (chilled or frozen) meat of cervids either farm-raised or harvested on a game farm or similar facility.* The meat is derived from cervids that were born after the region of origin implemented an effective ban on the feeding of ruminant protein to ruminants, that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and that were members of a herd not known to be infected with or exposed to a transmissible spongiform encephalopathy, and, if ground meat or sausage, is either all cervine meat or cervine meat mixed with nonruminant meat.

(i) *Fresh (chilled or frozen) meat from wild-harvested caribou, musk ox, or other cervids.* The meat is derived from wild caribou, musk ox, or other cervids and meets the following conditions:

(1) The animals from which the meat is derived were harvested within a jurisdiction specified by the Administrator for which the game and wildlife service of the jurisdiction has informed the Administrator either that the jurisdiction conducts no type of game feeding program, or has complied with, and continues to comply with, the ban on the feeding of ruminant protein to ruminants in the BSE minimal-risk region; and

(2) The meat is derived from cervids that were slaughtered at a facility that either slaughters only cervids eligible for entry into the United States or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.

(j) *Gelatin.* The gelatin is derived from the bones of bovines less than 30 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.

(k) *Ports.* All products to be brought into the United States under this section must, if arriving at a land border port, arrive at one of the following ports: Eastport, ID; Houlton, ME; Detroit (Ambassador Bridge), Port Huron, and Sault St. Marie, MI; International Falls, MN; Sweetgrass, MT; Alexandria Bay, Buffalo (Lewiston Bridge and Peace Bridge), and Champlain, NY; Pembina and Portal, ND; Derby Line and Highgate Springs, VT; and Blaine (Pacific Highway and Cargo Ops), Lynden, Oroville, and Sumas (Cargo), WA.

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

10. The authority citation for part 95 would continue to read as follows:

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

11. Section 95.1 would be amended by adding a new definition of *offal,* in alphabetical order, to read as follows:

§ 95.1 Definitions.

* * * * *

Offal. The parts of a butchered animal that are removed in dressing, consisting largely of the viscera and the trimmings, which may include, but are not limited to, brains, thymus, pancreas, liver, heart, kidney.

* * * * *

12. Section 95.4 would be amended as follows:

a. In paragraph (a), the words "paragraphs (c) through (f)" would be removed and the words "paragraphs (c) through (h)" would be added in their place.

b. In paragraph (b), the words "paragraphs (d) and (f)" would be removed and the words "paragraphs (d) and (h)" would be added in their place.

c. In paragraph (c)(4), the first sentence would be revised and a new sentence would be added after the final sentence to read as set forth below.

d. Paragraph (c)(6) would be revised to read as set forth below.

e. Paragraph (f) would be redesignated as paragraph (h).

f. New paragraphs (f) and (g) would be added to read as set forth below:

§ 95.4 Restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy.

* * * * *

(c) * * *

(4) Except for facilities in regions listed in § 94.18(a)(3) of this subchapter, if the facility processes or handles any material derived from mammals, the facility has entered into a cooperative service agreement executed by the operator of the facility and APHIS. * * * In facilities in regions listed in § 94.18(a)(3) of this subchapter, the inspections that would otherwise be conducted by APHIS must be conducted at least annually by a representative of the government agency responsible for animal health in the region.

* * * * *

(6) Each shipment to the United States is accompanied by an original certificate signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the region of export certifying that the conditions of paragraph (c)(1) through (c)(3) of this section have been met, except that, for shipments of animal feed from a region listed in § 18(a)(3) of this subchapter, the certificate may be signed by a person authorized to issue such certificates by the veterinary services of the national government of the region of origin.

* * * * *

(f) Tallow otherwise prohibited importation under paragraph (a)(1) of this section may be imported into the United States if it meets the following conditions:

(1) The tallow is composed of less than 0.15 percent protein;

(2) The tallow is derived from bovines that have not been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter;

(3) The bovines were less than 30 months of age when slaughtered and were born after the region of origin implemented an effective ban on the feeding of ruminant protein to ruminants;

(4) The bovines are not known to have been fed ruminant protein, other than milk protein, during their lifetime;

(5) The intestines were removed from each bovine at slaughter.

(6) The tallow is not derived from an animal that died otherwise than by slaughter;

(7) Each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated by or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraphs (f)(1) through (f)(6) of this section have been met; and

(8) The shipment, if arriving at a U.S. land border port, arrives at a port listed in § 94.19(k) of this subchapter.

(g) Offal derived from cervids that is otherwise prohibited importation under paragraph (a)(1) of this section may be imported if the following conditions are met:

(1) The offal is derived from cervids that were born after the region of origin implemented an effective ban on the feeding of ruminant protein to ruminants, that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and that were members of herd not known to be infected with or exposed to a transmissible spongiform encephalopathy;

(2) Each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated by or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (g)(1) of this section have been met; and

(3) The shipment, if arriving at a U.S. land border port, arrives at a port listed in § 94.19(k) of this subchapter.

* * * * *

Done in Washington, DC, this 29th of October 2003.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 03–27611 Filed 10–31–03; 2:30 pm]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–120–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A319, A320, and A321 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain Airbus Model A320 series airplanes, that currently requires an inspection to detect moisture and migrated bushings of the guide fittings of the safety locking pins of the passenger doors, removal of any moisture, application of grease, and reinstallation of any migrated bushing. That AD also requires installation of a greasing nipple on the guide fitting of the locking pin and on three telescopic rods on the passenger doors. This action would add a requirement for modification of the upper guide fitting of the locking pin, and would expand the applicability in the existing AD. The

Rules and Regulations

Federal Register
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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93 and 94

[Docket No. 03–058–1]

Change in Disease Status of Canada Because of BSE

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations by adding Canada to the list of regions where bovine spongiform encephalopathy exists because the disease has been detected in an animal in that region. This action prohibits or restricts the importation of ruminants that have been in Canada and meat, meat products, and certain other products and byproducts of ruminants that have been in Canada. This action is necessary to help prevent the introduction of bovine spongiform encephalopathy into the United States.

DATES: This rule is effective retroactively to May 20, 2003. We will consider all comments that we receive on or before July 28, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–058–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–058–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 03–058–1" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a neurological disease of cattle and is not known to exist in the United States. It appears that BSE is primarily spread through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Therefore, BSE could become established in the United States if materials carrying the BSE agent, such as certain meat, animal products, and animal byproducts from ruminants, are imported into the United States and are fed to ruminants in the United States. BSE could also become established in the United States if ruminants with BSE are imported into the United States.

Sections 94.18, 95.4, and 96.2 of the regulations prohibit or restrict the importation of certain meat and other animal products and byproducts from ruminants that have been in regions in which BSE exists or in which there is an undue risk of introducing BSE into the United States. Paragraph (a)(1) of § 94.18 lists the regions in which BSE exists. Paragraph (a)(2) lists the regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance. Paragraph (b) of § 94.18 prohibits the importation of fresh, frozen, and chilled meat, meat products, and most other edible products of ruminants that have been in any region listed in paragraphs (a)(1) or (a)(2). Paragraph (c) of § 94.18 restricts the importation of gelatin derived from ruminants that have been in any of these regions. Section 95.4 prohibits or restricts the importation of certain byproducts from ruminants that have been in any of those regions, and § 96.2 prohibits the importation of casings, except stomach casings, from ruminants that have been in any of these regions. Additionally, the regulations in part 93 pertaining to the importation of live animals provide that the Animal and Plant Health Inspection Service (APHIS) may deny an application for a permit for the importation of ruminants from regions where a communicable disease such as BSE exists and from regions that present risks of introducing communicable diseases into the United States (*see* § 93.404(a)(3)).

On May 20, 2003, the Canadian Food Inspection Agency reported a case of BSE in a beef cow in northern Alberta. Therefore, in order to prevent the introduction of BSE into the United States, we are amending § 94.18(a)(1) by adding Canada to the list of regions where BSE is known to exist. This action prohibits or restricts the importation of ruminants that have been in Canada and the importation of meat, meat products, and certain other products and byproducts of ruminants that have been in Canada. We are making this amendment effective retroactively to May 20, 2003, which is the date that Canada reported the BSE case.

As noted previously, the regulations in § 93.404(a)(3) provide the basis for APHIS to deny an application for a permit for the importation of ruminants from regions listed in § 94.18(a)(1) or (a)(2). Because, with certain exceptions, ruminants may not be imported into the

United States unless their importation is authorized by a permit, the provisions of § 93.404(a)(3) have been sufficient to prevent the entry of live ruminants from regions affected with BSE. However, the regulations in part 93 provide exemptions from the permit requirement for ruminants from several regions, including Canada, under certain circumstances. Given that the denial of a permit application may not serve in all cases to provide a regulatory basis for preventing the importation of ruminants from regions affected with BSE, we have amended the regulations in § 93.401, "General prohibitions; exceptions," to include an explicit prohibition on the importation of ruminants that have been in any region listed in § 94.18(a)(1) or (a)(2).

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the introduction of BSE into the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (*see* **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has retroactive effective to May 20, 2003; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR parts 93 and 94 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 93.401, paragraph (a) is revised to read as follows:

§ 93.401 General prohibitions; exceptions.

(a) No ruminant or product subject to the provisions of this part shall be brought into the United States except in accordance with the regulations in this part and part 94 of this subchapter;[3] nor shall any such ruminant or product be handled or moved after physical entry into the United States before final release from quarantine or any other form of governmental detention except in compliance with such regulations. Notwithstanding any other provision of this subpart, the importation of any ruminant that has been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter is prohibited. *Provided, however,* the Administrator may upon request in specific cases permit ruminants or products to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that such action will not endanger the livestock or poultry of the United States.

* * * * *

[3] Importations of certain animals from various regions are absolutely prohibited under part 94 because of specified diseases.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 3. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

§ 94.18 [Amended]

■ 4. In § 94.18, paragraph (a)(1) is amended by adding, in alphabetical order, the word "Canada,".

Done in Washington, DC, this 23rd day of May, 2003 .

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–13440 Filed 5–28–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 02–109–3]

Importation of Beef From Uruguay

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from Uruguay. Based on the evidence presented in a recent risk assessment, we believe that fresh (chilled or frozen) beef can be safely imported from Uruguay provided certain conditions are met. This action will provide for the importation of beef from Uruguay into the United States while continuing to protect the United States against the introduction of foot-and-mouth disease.

EFFECTIVE DATE: May 29, 2003.

FOR FURTHER INFORMATION CONTACT: Dr. Hatim Gubara, Senior Staff Veterinarian, Regionalization Evaluation Services Staff, VS, APHIS, 4700 River Road Unit

Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 01–094–1]

Change in Disease Status of Japan Because of BSE

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations by adding Japan to the list of regions where bovine spongiform encephalopathy exists because the disease has been detected in a native-born animal in that region. The effect of this action is restriction on the importation of ruminants that have been in Japan and meat, meat products, and certain other products of ruminants that have been in Japan. This action is necessary to help prevent the introduction of bovine spongiform encephalopathy into the United States.

DATES: This rule is effective retroactively to September 10, 2001. We invite you to comment on this docket. We will consider all comments that we receive by December 17, 2001.

ADDRESSES: Please send four copies of your comment (an original and three copies) to: Docket No. 01–094–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 01–094–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Chief Staff Veterinarian, National Center for Import and Export, Sanitary Issues Management Staff, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a neurological disease of bovine animals and other ruminants and is not known to exist in the United States. It appears that BSE is primarily spread through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Therefore, BSE could become established in the United States if materials carrying the BSE agent, such as certain meat, animal products, and animal byproducts from ruminants, are imported into the United States and are fed to ruminants in the United States. BSE could also become established in the United States if ruminants with BSE are imported into the United States.

Sections 94.18, 95.4, and 96.2 of the regulations prohibit or restrict the importation of certain meat and other animal products and byproducts from ruminants that have been in regions in which BSE exists or in which there is an undue risk of introducing BSE into the United States. In § 94.18, paragraph (a)(1) lists the regions in which BSE exists. Paragraph (a)(2) lists the regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance. Paragraph (b) of § 94.18 prohibits the importation of fresh, frozen, and chilled meat, meat products, and most other edible products of ruminants that have been in any region listed in paragraphs (a)(1) or (a)(2). Paragraph (c) of § 94.18 restricts the importation of gelatin derived from ruminants that have been in any of these regions. Section 95.4 prohibits or restricts the importation of certain byproducts from ruminants that have been in any of those regions, and § 96.2 prohibits the importation of casings, except stomach casings, from ruminants that have been in any of these regions. Additionally, the regulations in 9 CFR part 93 pertaining to the importation of live animals provide that the Animal and Plant Health Inspection Service may deny the importation of ruminants from regions where a communicable disease such as BSE exists and from regions that present risks of introducing communicable diseases into the United States (see § 93.404(a)(3)).

On September 10, 2001, Japan reported a suspected case of BSE in a native-born animal, and on September 22, 2001, Japan confirmed their diagnosis in a report to the Office International des Epizooties. Therefore, in order to reduce the risk of introducing BSE into the United States, we are amending § 94.18 (a)(1) by adding Japan to the list of regions where BSE is known to exist. The effect of this action is a restriction on the importation of ruminants that have been in Japan and on the importation of meat, meat products, and certain other products and byproducts of ruminants that have been in Japan. We are making this amendment effective retroactively to September 10, 2001, which is the date that BSE was reported in a native-born animal in that region.

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the introduction of BSE into the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register** that will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required under Executive Order 12866.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has retroactive effect to September 10, 2001; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7711, 7712, 7713, 7714, 7751, and 7754; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

§ 94.18 [Amended]

2. In § 94.18, paragraph (a)(1) is amended by adding, in alphabetical order, the word "Japan,".

Done in Washington, DC, this 10th day of October 2001.

W. Ron DeHaven,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01-25953 Filed 10-15-01; 8:45 am]

BILLING CODE 3410-34-U

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. 97-001TF]

RIN 0583-AC35

Elimination of Requirements for Partial Quality Control Programs; Certification of Scales

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its regulations governing the certification for accuracy of scales used in federally inspected meat and poultry establishments. Under the final rule, official establishments may rely on State or local certification or data from documented procedures that demonstrate compliance with the National Institute of Standards and Technology Handbook 44. This final rule addresses an issue raised after publication of the May 30, 2000, final rule "Elimination of Requirements for Partial Quality Control (PQC) Programs," by clarifying that establishments may rely on data from documented procedures, and that FSIS will verify establishment compliance with regulations on the accuracy of scales based on data maintained by the establishments.

EFFECTIVE DATE: This final rule is effective November 15, 2001.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Director, Regulations Development and Analysis Division, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 720-5627, fax number (202) 690-0486.

SUPPLEMENTARY INFORMATION:

Background

On May 30, 2000, FSIS published the final rule "Elimination of Requirements for Partial Quality Control Programs" (65 FR 34381). The final rule, which became effective August 28, 2000, removed from the Federal meat and poultry products inspection regulations the remaining requirements pertaining to partial quality control (PQC) programs. A PQC program, as distinguished from a total quality control (TQC) system, controls a single product, operation, or part of an operation in a meat or poultry establishment. A TQC system controls all products and processes in an establishment. The final rule removed the design requirements for PQC programs and the requirements for establishments to have PQC programs for certain products or processes. The final rule was intended to make the regulations more consistent with the Pathogen Reduction (PR)/Hazard Analysis and Critical Control Points (HACCP) regulations and to give federally inspected establishments greater flexibility to adopt new technologies and methods that will improve food safety and other consumer protections.

Status of Establishment PQC Programs

After publication of the final rule, some establishments asked the Agency whether they could continue to use their PQC programs, including PQC programs for net weight. Some persons who contacted the Agency asked specifically about the status of PQC programs that control net weight. Some establishments believed that, if such programs were rescinded, their products would be subject to lot inspection by FSIS. FSIS answered that the final rule does not rescind PQC programs for net weight. Establishments can continue to use PQC programs for net weight, and the Agency will verify their compliance with net weight requirements based on data from such programs.

Others asked whether the Agency would recognize TQC system data or PQC net weight program data regarding the testing of scales. They referred to the fact that the final rule removes the requirement for an establishment to have a total quality control (TQC) system provision for net weight or a partial quality control (PQC) program for net weight control in lieu of displaying, on or near its scales, a valid certification from a State or local weights and measures authority or from

(c) *Obtaining approval for exempt uses.* In order to receive exemptions for cherries or cherry products utilized for exempt purposes, handlers must apply to the Board for a new exemption or for renewal of an existing exemption by November 1 for the next succeeding year, except for the 1997 year only, handlers may apply through February 5, 1998. A handler shall have one crop year to dispose of cherries or cherry products to exempt outlets approved by the Board, unless granted a renewal. Handlers applying to the Board for a new exemption or for renewal of an existing exemption are subject to the following conditions:

(1) When applying to the Board for an exemption for new product development, handlers must detail the nature of their new product, how it differs from current, existing products and the anticipated short and long term sales volume for the exemption. It will be the Board staff's responsibility to analyze and investigate any request and upon completion of that analysis authorize or deny the exemption.

(2) When applying to the Board for an exemption for new market development, handlers must detail the nature of their new market, how it differs from current, existing markets and the anticipated short and long term sales volume for the exemption. It will be the Board staff's responsibility to analyze and investigate any request and upon completion of that analysis authorize or deny the exemption.

(3) When applying to the Board for an exemption for the development of export markets for tart cherries or cherry products (including juice and juice concentrate through June 30, 1998 only) in countries other than Canada, Mexico and Japan, including the expansion of sales in existing export markets, handlers must detail the nature of their product, specify whether such product differs from current products being sold in export markets, and estimate the anticipated short and long term sales volumes for the requested exemption.

(4) When applying to the Board for an exemption for experimental purposes, handlers must indicate the preliminary and/or developmental experimental activity. Such experimental purposes should be intended to result in new products, new applications and/or new markets for existing tart cherry products. Any exemption for experimental work shall be limited in scope, duration and volume which the proposing party shall specify at the time a request for exemption is made. In no case shall an exemption for experimental purposes last longer than five years or exceed 100,000 pounds raw product equivalent per handler of tart cherries during the duration of the experiment.

(d) *Review of applications.* A Board appointed subcommittee of three persons which shall include the manager (or a Board member acting in the Manager's stead), the public member and one industry person who is not on the Board, shall review applications for exemption or renewal of exemption and either approve or deny the exemption. Any denial of an application for exemption or renewal of an existing exemption shall be served on the applicant by certified mail and shall state the reasons for the denial. Within 10 days after the receipt of a denial, the applicant may file an appeal, in writing, with the Deputy Administrator, Fruit and Vegetable Programs, supported by any arguments and evidence the applicant may wish to offer as to why the application for exemption or renewal of exemption should have been approved. The Deputy Administrator upon consideration of such appeal will take such action as deemed appropriate with respect to the application for exemption or renewal of exemption.

(e) *Progress report.* Each handler that is granted an exemption must submit to the Board an annual progress report, due May 1 of each crop year. The progress report shall include the results of the exemption activity (comparison of intended activity with actual activity) for the year in its entirety, the volume of exempted fruit, an analysis of the success of the exemption program, and such other information as the Board may request.

(f) *Diversion credit; failure to meet terms and conditions of exemption.* Handler diversion certificates for exempt uses shall be issued to handlers provided that terms and conditions applicable to exempt uses are satisfied. Diversion certificates will not be issued to handlers for any volume of tart cherry products for which such terms and conditions are not satisfied and such cherries would be subject to all of the terms and conditions of §§ 930.41, 930.44, 930.51, 930.53, and §§ 930.55 through 930.57.

(g) *Failure to meet terms and conditions for exemption.* Upon termination of an exemption, any volume of tart cherry products that were granted an exemption but were not utilized for the authorized exempt purpose would be subject to all of the terms and conditions of §§ 930.41, 930.44, 930.51, 930.53, and §§ 930.55 through 930.57.

Dated: December 30, 1997.

Enrique E. Figueroa,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 98–283 Filed 1–5–98; 8:45 am]

BILLING CODE 3410–02–U

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 94 and 96

[Docket No. 97–127–1]

Restrictions on the Importation of Ruminants, Meat and Meat Products From Ruminants, and Certain Other Ruminant Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations governing the importation into the United States of ruminants, meat and meat products from ruminants, and other ruminant products to restrict the importation of live ruminants, meat and meat products from ruminants, and certain other ruminant products from countries in which bovine spongiform encephalopathy (BSE) may exist. This action is necessary to ensure that animals and animal products affected with BSE are not imported into the United States.

DATES: Interim rule effective December 12, 1997. Consideration will be given only to comments received on or before March 9, 1998.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 97–127–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 97–127–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Julia Sturm, Supervisory Staff Veterinarian, Products Program, National Center for Import and Export, VS, APHIS, USDA Center, Unit 40, 4700 River Road, Riverdale, MD 20737–1231, (301) 734–3399.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR parts 92, 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a neurological disease of bovine animals and other ruminants and is not known to exist in the United States.

It appears that BSE is primarily spread through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Therefore, BSE could become established in the United States if materials carrying the BSE agent, such as certain meat and other animal products and byproducts from ruminants infected with BSE, are imported into the United States and are fed to ruminants in the United States. BSE could also become established in the United States if ruminants from countries or other regions in which BSE exists are imported.

Sections 94.18, 95.4, and 96.2 of the regulations prohibit or restrict the importation of certain meat and other animal products and byproducts from ruminants that have been in regions in which BSE exists. These regions, which currently consist only of countries, are listed in § 94.18 of the regulations. Furthermore, § 93.404(a)(3) states that the Animal and Plant Health Inspection Service (APHIS) may deny the importation of ruminants from regions where a communicable disease such as BSE exists. The current regulations at § 94.18(a) list the following countries as regions in which BSE exists: Belgium, France, Great Britain, Northern Ireland, the Republic of Ireland, Luxembourg, The Netherlands, Oman, Portugal, and Switzerland.

We now consider it necessary to restrict the importation of ruminants, meat and meat products from ruminants, and certain ruminant products and byproducts not only from countries and other regions in which BSE is known to exist, but also from countries and other regions which, because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance, present a significant risk of introducing BSE. Specifically, we consider it necessary to apply these restrictions to all countries of Europe. In addition to the countries listed above, we are applying such restrictions to Albania, Austria, Bosnia-Herzegovina, Bulgaria, Croatia, the Czech Republic, Denmark, the Federal Republic of Yugoslavia, Finland, Germany, Greece, Hungary, Italy, the former Yugoslav Republic of Macedonia, Norway, Poland, Romania, the Slovak Republic, Slovenia, Spain, and Sweden.

Additionally, in this rule, in the list of regions in which BSE exists, we are including Great Britain and Northern Ireland under "United Kingdom," which also encompass The Falklands.

Reasons for New Restrictions

Our decision to establish the restrictions set forth in this interim rule is based on recent developments in Europe that lead us to believe that the BSE agent may be present, but as yet undetected, throughout Europe. The Netherlands, Belgium, and Luxembourg have recently reported their first cases of BSE in native-born cattle. Additionally, Belgium and Luxembourg have reported that cattle diagnosed with BSE were inadvertently processed into the animal food chain. Because of the movement of ruminants and ruminant products within Europe, the possibility exists that this potentially contaminated animal feed may have been moved from Belgium and Luxembourg to other European countries.

We consider the risk posed by this potential movement to be especially great in light of new scientific research that has identified BSE infectivity in bone marrow, dorsal root ganglion, and trigeminal ganglion. This new research expands the list of specific bovine tissues and organs of concern for BSE infectively. Previously, the list included only terminal (distal) ileum, brain, eye (retina), and spinal cord. Based on ongoing research, it appears likely that other tissues may contain the BSE infectious agent.

Therefore, we are amending the list in § 94.18(a) to include the countries discussed above. Due to the research findings that additional tissues may contain the BSE infectious agent, we are also amending § 94.18(b) to remove an exception that allowed fresh, frozen, and chilled meat and meat products to be imported into the United States from countries listed in § 94.18(a) if the meat was deboned, free of visually identifiable lymphatic and nerve tissue, and met certain other requirements.

In part 96 of the regulations, § 96.2(b) prohibits the importation of bovine casing, except stomachs, that originated in or were processed in any country where BSE exists, as listed in existing § 94.18(a). In this interim rule, we are rewording that reference in § 96.2(b) so that it also encompasses the countries we are adding to § 94.18(a) in this interim rule, and are changing the heading to the section accordingly. Additionally, we are expanding the prohibition on casings to include those from both bovines and other ruminants.

Because the following products present a minimal risk of BSE transmission, we have not been prohibiting their importation from BSE-affected countries under the existing regulations, and we are excluding them from the restrictions established by this interim rule: semen, milk and milk products, hides and skins, tallow and tallow derivatives, and certain blood products used in microbiologic media.

Procedures for Requesting Removal of Restrictions

In § 94.18(a)(3) of this rule, we provide that countries or other regions that wish to request removal from the list of regions considered high risk for BSE must submit to APHIS certain information described in § 92.2 of the regulations. This information is as follows:

1. The authority, organization, and infrastructure of the veterinary services organization in the region (country).
2. Disease status—i.e., is the BSE agent known to exist in the region? If "yes," at what prevalence? If "no," "when was the most recent diagnosis?
3. The status of adjacent regions with respect to the agent.
4. The extent of an active disease control program, if any, if the agent is known to exist in the region.
5. The degree to which the region is separated from regions of higher risk through physical or other barriers.
6. The extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity regarding such movements.
7. Livestock demographics and marketing practices in the region.
8. The type and extent of disease surveillance in the region—e.g., is it passive and/or active; what is the quantity and quality of sampling and testing?
9. Diagnostic laboratory capabilities.
10. Policies and infrastructure for animal disease control in the region—i.e., emergency response capacity.

Emergency Action

The Administrator of the Animal and Plant Health Inspection Service has determined that an emergency exists that warrants publication of this interim rule without prior opportunity for public comment. We are making this

action effective retroactively to December 12, 1997, which is the date APHIS issued a policy stating it had stopped issuing import permits for the live ruminants and ruminant products and byproducts covered by this interim rule. This effective date is necessary to ensure that ruminant and ruminant products and byproducts infected with BSE are not imported into the United States.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 533 to make the rule effective December 12, 1997. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This emergency situation makes compliance with section 603 and timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. If we determine this rule would have a significant economic impact on a substantial number of small entities, then we will discuss the issues raised by section 604 of the Regulatory Flexibility Act in our Final Regulatory Flexibility Analysis.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has retroactive effect to December 12, 1997; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB), and there are no new requirements. The assigned OMB control number is 0579-0040.

List of Subjects

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 96

Imports, Livestock, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR, chapter I, subchapter D, as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY; PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306, 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

§ 94.18 [Amended]

2. Section 94.18 is amended by revising the heading to the section and paragraphs (a) and (b) to read as follows:

§ 94.18 Restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy.

(a)(1) Bovine spongiform encephalopathy exists in the following regions: Belgium, France, the Republic of Ireland, Luxembourg, Oman, The Netherlands, Portugal, Switzerland, and the United Kingdom.

(2) The following regions, because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance, present and undue risk of introducing bovine spongiform encephalopathy into the United States: Albania, Austria, Bosnia-Herzegovina, Bulgaria, Croatia, the Czech Republic, Denmark, the Federal Republic of Yugoslavia, Finland, Germany, Greece, Hungary, Italy, the Former Yugoslav Republic of Macedonia, Norway, Poland, Romania, the Slovak Republic, Slovenia, Spain, and Sweden.

(3) A region may request at any time that the Administrator considers its removal from a list set forth in paragraphs (a)(1) or (a)(2) of this section by following the procedures set forth §§ 92.2(b) (1) through (4), 92.2(b) (5) through (11), and 92.2(c) of this chapter.

(b) Except as provided in paragraph (d) of this section, the importation of fresh, frozen, and chilled meat, meat products, and edible products other than meat (excluding gelatin, milk, and milk products), from ruminant that have been in any of the countries listed in paragraph (a) of this section is prohibited.

* * * * *

PART 96—RESTRICTION OF IMPORTATIONS OF FOREIGN ANIMAL CASINGS OFFERED FOR ENTRY INTO THE UNITED STATES

3. The authority citation for part 96 continues to read as follows:

Authority: 21 U.S.C. 111, 136, 136a; 7 CFR 2.22, 2.80, and 371.2(d).

§ 96.2 [Amended]

4. Section 96.2 is amended by revising the heading to the section and paragraph (b) to read as follows:

§ 96.2 Prohibition of casings due to African swine fever and bovine spongiform encephalopathy.

* * * * *

(b) The importation of casings, except stomachs, from bovines and other ruminants that orginated in or were processed in any region listed in § 94.18(a) of this subchapter is prohibited.

Done in Washington, DC, this 31st day of December 1997.

Joan M. Arnoldi,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98-266 Filed 1-5-98; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 558

New Animal Drugs and Related Products; Change of Sponsor; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of October 23, 1997 (62 FR 55159). The document amended the animal drug regulations to reflect a change of sponsor for three new animal drug applications (NADA's) and three abbreviated new animal drug applications (ANADA's) from Wade-Jones Co., Inc., and its manufacturing subsidiary Arkansas Micro Specialties,

the acreage will be the harvested production, or our reappraisal if the crop is not harvested; and

(2) All harvested production from the insurable acreage.

(e) Mature production of smooth green and yellow peas, lentils, and seed peas that do not qualify as contract seed peas under the policy terms, and that are not deliverable under the contract or are sold under the contract for less than the contract price, may be adjusted for quality deficiencies. No adjustment for quality deficiencies will be allowed for Austrian Winter Peas.

(1) Production will be eligible for quality adjustment if:

(i) Deficiencies in quality, in accordance with the United States Standards for Whole Dry Peas, Split Peas, and Lentils, result in production grading U.S. No. 2 or worse because of defects, color, skinned production (lentils only), odor, material weathering, or distinctly low quality; or

(ii) Substances or conditions are present that are identified by the Food and Drug Administration or other public health organizations of the United States as being injurious to human or animal health.

(2) Quality will be a factor in determining your loss only if:

(i) The deficiencies, substances, or conditions resulted from a cause of loss against which insurance is provided under these Crop Provisions and which occurs within the insurance period;

(ii) The deficiencies, substances, or conditions result in a net price for the damaged production that is less than the local market price;

(iii) All determinations of these deficiencies, substances, or conditions are made using samples of the production obtained by us or by a disinterested third party approved by us; and

(iv) The samples are analyzed by a grader licensed to grade dry peas under the authority of the United States Agricultural Marketing Act or the United States Warehouse Act with regard to deficiencies in quality, or by a laboratory approved by us with regard to substances or conditions injurious to human or animal health. Test weight for quality adjustment purposes may be determined by our loss adjuster.

(3) Dry Pea production that is eligible for quality adjustment, as specified in sections 12(e) (1) and (2), will be reduced as follows:

(i) The highest local market price for the qualifying damaged production will be determined on the earlier of the date such damaged production is sold or the date of final inspection for the unit. The highest local market price for the qualifying damaged production will be determined in the local area to the extent feasible. We may obtain prices from any buyer of our choice. If we obtain prices from one or more buyers located outside your local market area, we will reduce such prices by the additional costs required to deliver the dry peas to those buyers. Discounts used to establish the net value of the damaged production will be limited to those that are usual, customary, and reasonable.

The value will not be reduced for:

(A) Moisture content;

(B) Damage due to uninsured causes; or

(C) Drying, handling, processing, or any other costs associated with normal harvesting, handling, and marketing of the dry peas; except, if the value of the damaged production can be increased by conditioning, we may reduce the value of the production after it has been conditioned by the cost of conditioning but not lower than the value of the production before conditioning;

(ii) The value per pound of the damaged or conditioned production will be divided by the local market price to determine the quality adjustment factor;

(iii) The number of pounds of the damaged or conditioned production will then be multiplied by the quality adjustment factor to determine the production count to be included in section 12(d); and

(iv) Any production harvested from plants growing in the insured crop may be counted as production of the insured crop on a weight basis.

13. Prevented Planting.

Your prevented planting coverage will be 60 percent of your production guarantee for timely planted acreage. If you have limited or additional levels of coverage as specified in 7 CFR part 400, subpart T, and pay an additional premium, you may increase your prevented planting coverage to a level specified in the actuarial documents.

Signed in Washington, D.C., on December 9, 1997.

Kenneth D. Ackerman,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 97-32619 Filed 12-15-97; 8:45 am]

BILLING CODE 3410-08-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 97-034-3]

Change in Disease Status of The Netherlands Because of BSE

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that added The Netherlands to the list of countries where bovine spongiform encephalopathy (BSE) exists. We took this action because BSE was detected in a cow in The Netherlands. The effect of the interim rule was to prohibit or restrict the importation of live ruminants and certain fresh, chilled, and frozen meat, and certain other animal products and animal byproducts from ruminants which have been in The Netherlands. The interim rule was necessary to reduce the risk that BSE could be introduced into the United States.

EFFECTIVE DATE: The interim rule was effective on March 21, 1997.

FOR FURTHER INFORMATION CONTACT: Dr. John Cougill, Staff Veterinarian, Animal Products Program, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231, (301) 734-3399; or e-mail: jcougill@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

In an interim rule effective April 10, 1997, and published in the **Federal Register** on April 15, 1997 (62 FR 18263-18264, Docket No. 97-034-1), we amended our regulations by adding The Netherlands to the list of countries where BSE exists. We took this action because BSE was detected in a cow born in The Netherlands. We also published another interim rule in the **Federal Register** on May 7, 1997 (62 FR 24802, Docket No. 97-034-2), that changed the effective date of the April 1997 interim rule from April 10, 1997, to March 21, 1997. The change in effective date was necessary to ensure that the prohibitions and restrictions established by the April 1997 interim rule applied to animal products and byproducts that were shipped to the United States from The Netherlands between March 21, 1997, when BSE was detected in The Netherlands, and April 10, 1997, when the first interim rule was signed.

Comments on the interim rule were required to be received on or before June 16, 1997. We received two comments by that date. They were from a company that imports cattle semen and an importer of meat and meat byproducts. They are discussed below.

The commenters did not oppose adding The Netherlands to the list of countries where BSE exists. However, one comment expressed concerns about Animal and Plant Health Inspection Service regulations that restrict the importation of veal from countries where BSE is known to exist. The other comment concerned the trade protocols of the United States and other countries for importing cattle semen from countries where BSE exists. Both comments are outside the scope of the interim rule. However, we continually review and update our regulations to make them consistent with current scientific data. We will consider these comments as we review our regulations. If we decide to make any changes to our regulations in response to these comments, we will publish a proposed rule in the **Federal Register**.

Therefore, based on the rationale set forth in the April 1997 interim rule, we are affirming the provisions of the interim rule without change.

This action also affirms the information contained in the interim rule concerning Executive Orders 12866 and 12988 and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived the review process required by Executive Order 12866.

Regulatory Flexibility Act

This rule affirms an interim rule that amended our regulations by adding The Netherlands to the list of countries where BSE exists. We took this action because BSE was detected in a cow in that country. The effect of the interim rule was to prohibit or restrict the importation of certain fresh, chilled, and frozen meat, and certain other animal products and animal byproducts from ruminants which have been in The Netherlands. The interim rule was necessary to reduce the risk that BSE could be introduced into the United States.

BSE is a slowly progressing fatal degenerative disease that affects the central nervous system of cattle. The disease was first diagnosed in 1986 in Great Britain, where it is sometimes called "mad cow disease." Infected animals may display changes in temperament, abnormal posture, incoordination and difficulty in rising, decreased milk production, and loss of body condition despite continued appetite. The causative agent of BSE is not completely characterized, and there is no treatment for the disease. At the current time, the disease is not known to exist in the United States. There is no vaccine to prevent BSE nor is there a test to detect the disease in live animals. Given those factors, the import restrictions imposed by the interim rule are the most effective means available for ensuring that BSE does not enter the United States from The Netherlands.

Preventing the introduction of BSE into the United States is critical. In addition to the potential threat to public health, BSE also has the potential to cause severe economic hardship for the U.S. livestock industry. Great Britain's experience with the disease provides an insight into how damaging BSE can be to livestock. Between November 1986 (when BSE was first diagnosed in Great Britain) and May 1996, an estimated 160,540 head of cattle in approximately 33,455 herds were diagnosed with BSE in Great Britain. The epidemic peaked there in January 1993, with almost 1,000 new cases per week. All of the animals in Great Britain showing signs of BSE, most of which were dairy cows between 3 and 5 years of age, were destroyed.

If BSE were introduced into the United States, livestock losses would likely be much greater than in Great Britain, because the United States raises more cattle. However, assuming the same number of cattle losses in the United States as in Great Britain (160,540), the introduction of BSE into the United States would cost U.S. livestock producers $177 million, based on the current price of $1,100 per head for dairy cows. The $177 million figure does not include higher production costs that would likely be incurred by U.S. producers, due to the presence of the disease.

U.S. export and consumer markets would also be affected. The United States currently restricts the importation of live ruminants and ruminant products from all countries where BSE is known to exist. Presumably, if BSE were introduced into the United States, other countries would adopt similar restrictions on the exportation of live ruminants and ruminant products from the United States. Such restrictions by other countries would be devastating economically. In 1993, for example, the dollar value of U.S. exports of both bovine animals and bovine animal meat totaled $2.1 billion. Those export sales could be lost in their entirety. Consumers would incur higher costs due to higher prices for ruminant products and increased prices for competitive products, such as poultry.

We expect that restricting the importation of live ruminants and ruminant products from The Netherlands will have little or no impact on U.S. consumers. This is because The Netherlands does not export live ruminants to the United States. Also, U.S. imports of ruminant products from The Netherlands are minimal when compared against total U.S. imports or overall U.S. supply (imported and domestically produced) of those commodities. In 1996, the volume of ruminant products imported from The Netherlands, categorized into seven broad product groups, was as follows: 149,906 kilograms (kg) of fresh or frozen beef with bone; 2,060 kg of prepared or preserved beef; 307,259 kg of variety meats; 458 cattle embryos; 3,016,847 kg of miscellaneous animal products; and 1,587,244 kg of animal feed. These seven product groups represent 40 subcategories of products imported from The Netherlands. For most subcategories, The Netherlands' share of the total U.S. imports of that product was 1 percent or less. The Netherlands' share exceeded 10 percent of the total U.S. imports in only 5 subcategories. However, even for those 5 product subcategories, The Netherlands' share of overall U.S. supply was not significant. Because The Netherlands is not a significant supply source for the U.S. market, restrictions on imports from The Netherlands should not have a significant effect on consumer prices in the United States.

The Regulatory Flexibility Act requires that agencies consider the economic impact of rule changes on small entities. We expect the interim rule will have little or no impact on small entities in the United States because imports of ruminants and ruminant products from The Netherlands affected by this interim rule have been minimal in the past. Small brokers, agents, and others in the United States who are directly involved in the importation and sale of ruminant products from The Netherlands should be able to obtain substitutes from alternative sources. We were unable to determine the number of small entities engaged in these activities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR part 94 and that was published at 62 FR 18263–18264 on April 15, 1997.

Authority: 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306, 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

Done in Washington, DC, this 10th day of December 1997.

Craig A. Reed,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–32779 Filed 12–15–97; 8:45 am]

BILLING CODE 3410–34–P

Rules and Regulations

Federal Register
Vol. 56, No. 235
Friday, December 6, 1991

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

Prevailing Rate Systems

AGENCY: Office of Personnel Management.

ACTION: Interim rule with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing an interim regulation to abolish the Imperial, California, Nonappropriated Fund (NAF) wage Area and to define it as an area of application to the Yuma, Arizona, NAF wage area. The Imperial County, California, survey area does not have the required minimum of 26 NAF wage employees, and no local activity has the capability to conduct a wage survey.

DATES: This interim rule becomes effective on December 6, 1991. Comments must be received on or before January 6, 1992.

ADDRESSES: Send or deliver comments to Barbara L. Fiss, Assistant Director for Pay Policy and Programs, Personnel Systems and Oversight Group, U.S. Office of Personnel Management, room 6H31, 1900 E Street, NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Brenda Roberts (202) 606–2848 or (FTS) 266–2848.

SUPPLEMENTARY INFORMATION: Imperial County, California, is presently defined as a separate wage area for NAF pay-setting purposes. The Department of Defense notified OPM that Imperial County, California, no longer meets the regulatory criteria for an established nonappropriated fund wage area under § 532.219 of title 5, Code of Federal Regulations. The Imperial County, California, survey area does not have the required minimum of 26 NAF wage employees, and no local activity has the capability to conduct a wage survey.

The following criteria are taken into consideration when two or more counties are to be combined to constitute a single wage area:

(1) Proximity of largest activity in each county;

(2) Transportation facilities and commuting patterns; and

(3) Similarities of the counties in:

(i) Overall population;

(ii) Private employment in major industry categories; and

(iii) Kinds and sizes of private industrial establishments.

Based on a review of the criteria for combining wage areas, we find that the Imperial, California, wage area should be abolished and that Imperial County, California, should be defined as an area of application to the Yuma, Arizona, wage area. The Federal Prevailing Rate Advisory Committee reviewed this request and recommended approval by consensus.

Pursuant to sections 553 (b)(3)(B) and (d)(3) of title 5, United States Code, I find that good cause exists for waiving the general notice of proposed rulemaking and for making these regulations effective in less than 30 days. Imperial County, California, does not meet the current criteria for establishing nonappropriated fund wage areas.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they affect only Federal agencies and employees.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Government employees, Wages.

U.S. Office of Personnel Management.

Constance Berry Newman,

Director.

Accordingly, OPM is amending 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552, Freedom of Information Act, Pub. L. 92–502.

2. In appendix D to subpart B, the listing for the Imperial, California, wage area is to be removed from the list.

3. Appendix D to subpart B is amended by revising the wage area listing for Yuma, Arizona, to read as follows:

Appendix D to Subpart B of Part 532—Nonappropriated Fund Wage and Survey Areas

* * * * *

Arizona Yuma Survey Area
Arizona:
Yuma
Area of Application. Survey area plus
California:
Imperial

* * * * *

[FR Doc. 91–29226 Filed 12–5–91; 8:45 am]
BILLING CODE 6325–01–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 94 and 95

[Docket No. 91–104]

Importation of Animal Products and Byproducts from Countries Where BSE Exists

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are affirming with changes an interim rule that adds a list of countries where bovine spongiform encephalopathy (BSE) exists, and prohibits or restricts the importation of certain fresh, chilled, and frozen meat, and certain other animal products and

animal byproducts from ruminants which have been in a country where BSE exists. This action is necessary to reduce the risk that BSE could be introduced into the United States. This change will affect persons seeking to import the articles described above.

DATES: Final rule effective December 6, 1991.

FOR FURTHER INFORMATION CONTACT: Dr. John Grey, Senior Staff Veterinarian, Import-Export Products Staff, VS, APHIS, USDA, room 756, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-7885.

SUPPLEMENTARY INFORMATION:

Background

A neurological disease of bovine animals and other ruminants called bovine spongiform encephalopathy (BSE) has been identified in France, Great Britain, Northern Ireland, the Republic of Ireland, Oman, and Switzerland. Since the disease was first identified in 1986 there have been over 23,300 cattle on over 10,400 farms in Great Britain that have died or been destroyed as a result of BSE infection. BSE has also been found to affect a small number of ungulates in zoos in Great Britain. At the present time, BSE is not known to exist in the United States.

At our present state of knowledge about the disease, it appears that BSE in bovine animals and other ruminants may be caused by the same agent that causes the disease scrapie in sheep and goats. The major means of spread of BSE appears to be through the use of ruminant feed containing meat and other products from ruminants infected with BSE, and through use of veterinary biologic products which contain byproducts from ruminants infected with BSE.

We have promulgated regulations to control the risk that BSE could spread to the United States. In an interim rule published in the **Federal Register** on April 30, 1991 (56 FR 19794–19796, Docket No. 90–252), we amended 9 CFR parts 94 and 95 by adding import restrictions for certain meat, products, and byproducts from ruminants that have been in countries where BSE exists, and we listed France, Great Britain, Northern Ireland, the Republic of Ireland, Oman, and Switzerland as countries where BSE exists.

The interim rule announced that we would accept comments on these regulatory changes if they were received on or before July 1, 1991. We received 13 comment letters by the closing date, submitted by animal disease researchers, importers, and representatives of foreign governments. The comments, and changes we are making to the interim rule in response to them, are discussed below.

Comments On the Interim Rule

Comment: It is not clear in the interim rule whether the term "edible products other than meat from ruminants" in § 94.18 would include milk and milk products for human consumption. If so, this would prohibit the importation into the United States of a large volume of milk and milk products.

Response: The term "edible products other than meat" was not intended to include milk or milk products, and read in context the term applies to products that result from the slaughter of ruminants, not from milking. We are changing the term in § 94.18 to read "edible products other than meat (excluding gelatin, milk, and milk products)" to remove any possible confusion on this point. The exclusion regarding gelatin is explained below.

Comment: Section 94.18 appears to prohibit the importation of any edible quality gelatin from the listed countries where BSE exists. Gelatin from Europe does not pose a risk of spreading BSE because it is made from the hides and bones of slaughtered animals that were found healthy and fit for consumption through ante mortem and post mortem inspections. In addition, the process of making gelatin would destroy the BSE agent. Bones used in gelatin have the fat and marrow removed through intensive hot water treatment, and are then subjected to 5–6 days in an acid bath (4–6 percent hydrochloric acid) followed by 50–60 days in a lime pit (Ph over 12.5).

Response: As discussed below, we are changing the regulations to allow the importation of gelatin for certain uses which should not pose a risk of spreading BSE, provided the imports are made under specified conditions. However, we do not agree that any of the reasons cited above demonstrate that gelatin presents no risk of spreading BSE. Ante mortem inspections of animals will not reveal BSE if the animal is in an early stage of infection and has not yet developed symptoms. Post mortem examination that does not include sophisticated microscopic examination of brain tissues will not reveal BSE.

While currently available scientific knowledge about deactivation of the BSE agent suggests that the methods for making gelatin (particularly the lime treatment) should reduce the infectivity of any BSE agent present, we have not seen any thorough scientific studies that show that the procedures employed in gelatin manufacture will completely and reliably inactivate the BSE agent.

Comment: A large volume of edible quality gelatin from countries where BSE exists is imported into the United States for use in human food, human pharmaceuticals, and photography. These non-animal uses do not present a risk of spreading BSE, and importation of gelatin for these purposes should be allowed.

Response: We agree that gelatin imported from countries where BSE exists would present a risk only if it comes in contact with ruminants in the United States, and that gelatin imports for uses that do not bring the product in contact with ruminants should be allowed. However, it is important to ensure that gelatin imported for certain specified uses is actually devoted to those uses. Therefore, we are changing § 94.18 of the regulations to allow gelatin for human food, human pharmaceutical products, photography, and other uses that will not result in the gelatin coming in contact with ruminants to be imported from countries where BSE exists. The importer of the gelatin must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors to import the gelatin, and the permit application must state the intended use for the gelatin and the name and address of the consignee. This information will allow APHIS to confirm that the gelatin is used in a manner that will not result in the gelatin coming in contact with ruminants.

Comment: Many extracts and products from ruminant organs are imported into the United States for use in cosmetics. This non-animal use does not represent a risk of spreading BSE, but the language in § 95.4 bans imports of offal, fat, glands, and serum from ruminants in countries where BSE exists. This seems to be a total ban on imports of such cosmetics products. These products should be allowed to be imported.

Response: The regulations do not affect imports of fully processed cosmetic products that are packaged and ready for sale to consumers. The language in § 95.4 does prohibit import of certain ruminant glands and organs that are the raw material for many cosmetic products; that is because these materials represent a high risk of spreading BSE. We agree that products from ruminants, used only for cosmetic manufacture, do not represent a significant risk of spreading BSE if imported into the United States.

Therefore, we are adding language to § 95.4 stating that certain listed products may be imported into the United States for use as ingredients in cosmetics. The products are collagen, collagen products, amniotic liquids or extracts, placental liquids or extracts, serum albumin, and serocolostrum, derived from ruminants that have been in any country where BSE exists.

The importer of the products must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors to import the products, and the permit application must state the intended use for the products and the name and address of the consignee. This information will allow APHIS to confirm that the products are used as ingredients in cosmetics.

Comment: The regulations prohibit the importation of meat from countries where BSE exists unless the bones have been removed. The regulations should be changed to allow importation of bone-in meat if the ruminants providing the meat come from premises which have not had a case of BSE reported for two years. This restriction would be consistent with the Commission of the European Communities decision of June 8, 1990, which allows shipments of bone-in bovine meat from the United Kingdom to other European Economic Community member states if the meat is certified as being derived from bovines which are not from holdings in which BSE has been confirmed in the previous two years.

Response: We are not changing the regulations in response to this comment to allow the importation of bone-in meat in general from countries where BSE exists; however, we are changing the regulations to allow the importation of some classes of bone-in meat that represent minimal risks. Bones from ruminants with BSE are known to present a high risk of spreading BSE. Due to the lengthy incubation period during which an animal may be infected with BSE without showing any signs of the disease, two years without a diagnosis of BSE on a premises does not demonstrate that a premises is free of BSE. In addition, attempting to monitor two different types of meat imports from countries where BSE exists (boneless meat, and bone-in meat from certain premises) would impose major administrative difficulties and would present a risk that some shipments of bone-in meat from premises with BSE could inadvertently be imported. We believe that, in general, requiring removal of bones from ruminant meat from countries where BSE exists is the most reasonable and comprehensively effective way to control the risk associated with ruminant bones from such countries.

However, several commenters brought to our attention that ruminants of the family *Cervidae* (deer and related species) have not been diagnosed with BSE in the countries where BSE exists. For that reason, at this time we consider deer meat to present a very low risk of spreading BSE. Therefore we are changing § 94.18 of the regulations to allow the importation of meat derived from animals in the family *Cervidae*, whether boneless or containing bones. To address the slight risk that such imported meat might spread BSE, the meat must be accompanied by a certificate stating that the meat was derived from wild animals, or from farm-raised animals that have never been fed ruminant protein.

There is a slight risk that animals in the family *Cervidae* may become infected with BSE. If this occurs, we believe that importation of products from these animals other than meat and byproducts from these animals would present a significantly higher probability of introducing BSE than would be presented by importation of meat. Therefore, we are keeping the restrictions in § § 94.18 and 95.4 that apply to importation of edible products other than meat, and byproducts, from animals in the family *Cervidae* (as well as all other ruminants).

Comment: The rule does not adequately take into account that products from countries with many thousands of cases of BSE, like the United Kingdom, present a higher risk than products from countries with only a few reported cases. Products from "low-risk" countries should be subject to less stringent controls.

Response: We are not changing the regulations in response to this comment. BSE is not known to occur in the United States, and its introduction would be a major economic disaster for our animal industries. We believe that due to the drastic consequences of BSE introduction, strict import requirements are justified to control even very low-probability risks of introducing BSE. In addition, due to the long incubation period of BSE and the lack of long-term, comprehensive studies of its spread in countries with only a few reported cases, we cannot accurately estimate the extent of BSE in countries with any reported cases.

Comment: The supplementary information of the interim rule stated that BSE has been found to affect a small number of deer in Great Britain. This is incorrect. The six zoo animals affected were not deer, but antelope (ungulates of the family *Bovidae*).

Response: We apologize for this misstatement, and have corrected it in the supplementary information section of this final rule. Changes to the final rule affecting deer are discussed in a comment above.

Comment: Section 94.18 of the interim rule requires that ruminants be examined prior to slaughter "by a salaried veterinarian employed by the national government of the country in which the ruminants were slaughtered." The Ministry of Agriculture, Fisheries and Food in Great Britain, employs veterinary surgeons as Local Veterinary Inspectors (LVIs) on a fixed-fee basis to carry out many of its executive functions, including ante mortem inspection and certification. We therefore request a change to the regulations to permit LVIs to provide the appropriate export certification.

Response: We are removing the word "salaried" from the language of § 94.18 in response to this comment. It is the intent of APHIS to allow veterinarians who are employed by national governments to carry out animal health inspection and certification functions for export purposes to perform the examination required by § 94.18.

Comment: The interim rule does not specifically address shipments of products that would be excluded entry into the United States by the rule, but that would be allowed to transit the United States en route to their final destination. Language should be added allowing such transit under appropriate controls to prevent introduction of BSE into the United States while in transit.

Response: We agree that shipments of products that would be excluded entry into the United States under the regulations may safely transit the United States under appropriate restrictions. We are adding a new paragraph titled "Transit shipment of articles" to § § 94.18 and 95.4, which provides that such transit shipments may be made if the following conditions are met:

- The person moving the articles must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors permit by filing a permit application on VS form 16-3. (The address where the forms may be obtained is set forth in footnotes referenced in § § 94.18 and 95.4.)
- The articles must be sealed in leakproof containers bearing serial numbers during transit. Each container must remain sealed during the entire time that it is in the United States.

• The person moving the articles shall notify, in writing, the Plant Protection and Quarantine Officer at both the place in the United States where the articles will arrive and the port of export prior to such transit. The notification must include the:

(1) United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors permit number;

(2) Times and dates of arrival in the United States;

(3) Times and dates of exportation from the United States;

(4) Mode of transportation; and

(5) Serial numbers of the sealed containers.

• The articles must transit the United States in Customs bond.

Comment: The interim rule imposes more severe restrictions on products from countries where BSE exists than were imposed on such trade by member states of the European Economic Community. The severity of the interim rule exceeds what is necessary to protect animal health and amounts to an unwarranted barrier to international trade.

Response: We do not agree that the regulations are unnecessarily severe. As discussed above, introduction of BSE into the United States would cause major economic disruption, and we believe we are warranted in imposing regulations to control even low-probability risks that this could occur. We considered and rejected both more and less severe alternatives, including a total ban on ruminant products from countries where BSE exists, and adopted the alternative which we believe will best protect animal health in the United States while minimizing economic impacts both in the United States and abroad.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

As an alternative to the provisions of this rule, we have considered taking no action, and enforcing the current import regulations. This alternative was rejected because it would allow meat, animal products, and animal byproducts that might spread BSE to be imported into the United States.

The provisions of this rule will not have a significant economic impact on large or small entities. The only businesses affected will be a small number of importers of meat, products, and byproducts of ruminants which have been in a country where BSE exists. Alternative sources for these products are available in the United States.

Several commenters on the interim rule noted that the economic analysis for that rule would be inaccurate if the rule resulted in prohibiting the importation of gelatin or cosmetics ingredients from countries where BSE exists. Both of these are multimillion dollar import industries. As explained in this final rule, we are continuing to allow imports of these products from countries where BSE exists under specified conditions.

In recent years no fresh, chilled, or frozen beef has been imported from France, Great Britain, Northern Ireland, Oman, or Switzerland. A small amount of beef was imported from the Republic of Ireland in recent years; the value of these imports for the period 1987–88 was only $1,300,000. Recently one plant in Northern Ireland has applied to export beef to the United States. If this plant is approved, it will bear additional deboning and preparation costs for meat exported to the United States, to ensure that the meat meets the requirements of this rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

In accordance with section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, *et seq.*), the information collection provisions that are included in this rule have been approved by the Office of Management and Budget (OMB) and have been given OMB control number 0579-0015.

List of Subjects

9 CFR Part 94

African swine fever, Animal diseases, Exotic Newcastle disease, Foot-and-mouth disease, Fowl pest, Garbage, Hog cholera, Imports, Livestock and livestock products, Meat and meat products, Milk, Poultry and poultry products, Rinderpest, and Swine vesicular disease.

9 CFR Part 95

Animal byproducts, Animal diseases, Imports, Livestock and livestock products.

Accordingly, the regulations in 9 CFR parts 94 and 95 are amended as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), NEWCASTLE DISEASE (AVIAN PNEUMOENCEPHALITIS), AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 147a, 150ee, 161, 162, 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, and 134f; 31 U.S.C. 9701; 42 U.S.C. 4331, 4332; 7 CFR 2.17, 2.51, and 371.2(d).

2. Section 94.18 is revised to read as follows:

§ 94.18 Ruminant meat and edible products from ruminants that have been in countries where bovine spongiform encephalopathy exists.

(a) Bovine spongiform encephalopathy exists in the following countries: France, Great Britain, Northern Ireland, the Republic of Ireland, Oman, and Switzerland.

(b) Except as provided in paragraph (d) of this section, the importation of fresh, frozen, and chilled meat, and edible products other than meat (excluding gelatin, milk, and milk products), from ruminants that have been in any country listed in paragraph (a) of this section is prohibited unless the articles are accompanied by an accurate certificate of a veterinarian employed by the national government of the country in which the ruminants were slaughtered stating that the following conditions have been met:

(1) If fresh, frozen, and chilled meat derived from animals in the family *Cervidae*, the meat was derived either from wild animals, or from farm-raised animals that have never been fed ruminant protein;

(2) For articles other than those identified in paragraph (b)(1) of this section:

(i) all bones and visually identifiable lymphatic tissue and nerve tissue have been removed from the meat or edible product other than meat;

(ii) the meat or edible product other than meat is from ruminants that have not been in any country listed in paragraph (a) of this section during a period of time when the country permitted the use of ruminant protein in ruminant feed; and

(iii) the ruminants were examined prior to slaughter by a veterinarian employed by the national government of the country in which the ruminants were slaughtered, and found not to display any signs indicative of a neurological disorder.

(c) *Gelatin.* The importation of gelatin derived from ruminants that have been in any country listed in paragraph (a) of this section is prohibited unless the following conditions have been met:

(1) The gelatin must be imported for use in human food, human pharmaceutical products, photography, or some other use that will not result in the gelatin coming in contact with ruminants in the United States.

(2) The person importing the gelatin must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16–3.[1]

(3) The permit application must state the intended use of the gelatin and the name and address of the consignee in the United States.

(d) *Transit shipment of articles.* Fresh, chilled, or frozen meat, and edible products other than meat, that are prohibited importation into the United States in accordance with this section may transit the United States for immediate export if the following conditions are met:

(1) The person moving the articles must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16–3.[2]

(2) The articles must be sealed in leakproof containers bearing serial numbers during transit. Each container must remain sealed during the entire time that it is in the United States.

(3) The person moving the articles shall notify, in writing, the Plant Protection and Quarantine Officer at both the place in the United States where the articles will arrive and the port of export prior to such transit. The notification must include the:

(i) United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors permit number;

(ii) Times and dates of arrival in the United States;

(iii) Times and dates of exportation from the United States;

(iv) Mode of transportation; and

(v) Serial numbers of the sealed containers.

(4) The articles must transit the United States in Customs bond.

(Approved by the Office of Management and Budget under control number 0579-0015)

[1] VS form 16–3 may be obtained from the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Import-Export Products, Federal Building, Hyattsville, Maryland 20782.

[2] VS form 16–3 may be obtained from the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Import-Export Products, Federal Building, Hyattsville, Maryland 20782.

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

3. The authority citation for part 95 continues to read as follows:

Authority: 21 U.S.C. 111; 31 U.S.C. 9701; 7 CFR 2.17, 2.51, and 371.2(d).

§ 95.1 [Amended]

4. In § 95.1, the definitions of "Administrator," "Animal and Plant Health Inspection Service," and "United States" are revised to read as follows:

* * * * *

Administrator means the Administrator, Animal and Plant Health Inspection Service, or any individual authorized to act for the Administrator.

Animal and Plant Health Inspection Service means the Animal and Plant Health Inspection Service of the United States Department of Agriculture.

United States means the several States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other territories and possessions of the United States.

5. Section 95.4 is revised to read as follows:

§ 95.4 Bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants that have been in countries where bovine spongiform encephalopathy exists.

(a) Except as provided in paragraphs (c) and (d) of this section, the importation of bone meal, blood meal, meat meal or tankage, offal, fat, and glands from ruminants that have been in any country listed in § 94.18 of this chapter, is prohibited.

(b) Except as provided in paragraphs (c) and (d) of this section, the importation of serum from ruminants that have been in any country listed in § 94.18 of this chapter is prohibited, except that serum from ruminants may be imported for scientific, educational, or research purposes if the Administrator determines that the importation can be made under conditions that will prevent the introduction of bovine spongiform encephalopathy into the United States. Serum from ruminants imported in accordance with this paragraph must be accompanied by a permit issued by the Animal and Plant Health Inspection Service in accordance with § 104.4 of this chapter, and must be moved and handled as specified on the permit.

(c) *Articles for cosmetics.* The importation of collagen, collagen products, amniotic liquids or extracts, placental liquids or extracts, serum albumin, and serocolostrum, derived from ruminants that have been in any country listed in § 94.18 of this chapter is prohibited unless the following conditions have been met:

(1) The article must be imported for use as an ingredient in cosmetics.

(2) The person importing the article must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16–3.[1]

(3) The permit application must state the intended use of the article and the name and address of the consignee in the United States.

(d) *Transit shipment of articles.* Articles that are prohibited importation into the United States in accordance with this section may transit the United States for immediate export if the following conditions are met:

(1) The person moving the articles must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16–3.[2]

(2) The articles must be sealed in leakproof containers bearing serial numbers during transit. Each container must remain sealed during the entire time that it is in the United States.

(3) The person moving the articles shall notify, in writing, the Plant Protection and Quarantine Officer at both the place in the United States where the articles will arrive and the

[1] VS form 16–3 may be obtained from the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Import-Export Products, Federal Building, Hyattsville, Maryland 20782.

[2] VS form 16–3 may be obtained from the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Import-Export Products, Federal Building, Hyattsville, Maryland 20782.

port of export prior to such transit. The notification must include the:

(i) United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors permit number;

(ii) Times and dates of arrival in the United States;

(iii) Times and dates of exportation from the United States;

(iv) Mode of transportation; and

(v) Serial numbers of the sealed containers.

(4) The articles must transit the United States in Customs bond.

(Approved by the Office of Management and Budget under control number 0579-0015)

Done in Washington, DC, this 29th day of November, 1991.

Robert Melland,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 91-29182 Filed 12-5-91; 8:45 am]

BILLING CODE 3410-34-F

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 26700; Amdt. No. 1467]

Standard Instrument Approach Procedures: Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: *Effective:* An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which affected airport is located; or

3. The Flight Inspection Field Office which originated the SIAP.

For Purchase—

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA-200), FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, US Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS-420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC)/Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the Federal Register expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction of charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The Provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/P NOTAM for each SIAP. The SIAP information in some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FDC/P NOTAMs, the respective FDC/T NOTAMs have been cancelled.

The FDC/P NOTAMs for the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these chart changes to SIAPs by FDC/P NOTAMs, the TERPs criteria were applied to only these specific conditions existing at the affected airports.

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. All SIAP amendments in this rule have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a

possession or under their control a quantity of almonds necessary to meet their reserve obligations, less the quantity of almonds for which they have received reserve credits which have not been transferred to another handler and less any quantity for which they have otherwise been relieved by the Board of the responsibility to so hold.

Section 981.455(b) of the rules and regulations established under the order also currently provides that transferred reserve credit shall not exceed the quantity needed by the receiving handler to cover that handler's reserve obligation, that the Board shall complete the transfer of reserve credits upon receipt of an ABC Form 11 executed by both handlers, and that no transfer of reserve credits shall be made to satisfy a handler's inedible disposition obligation incurred pursuant to § 981.42(a) of the order. These provisions will continue to govern reserve credit transfers.

Notice of this action was published in the **Federal Register** on February 21, 1991 [56 FR 6998]. Written comments were invited through March 8, 1991. No comments were received.

Based on the above, the Administrator of the AMS has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

The information collection requirements contained in this rule have been previously approved by the Office of Management and Budget (OMB) and assigned OMB control number 0581–0071.

After consideration of all relevant matter presented, the information and recommendations submitted by the Board, and other available information, it is found that this final rule will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** because: (1) Handlers are currently disposing of 1990–91 crop year reserve almonds and earning reserve credits; (2) some handlers have indicated that they would like to utilize this provision as soon as possible; (3) this action relieves a restriction on handlers; (4) handlers are aware of this action and need no additional time to comply; and (5) no useful purpose would be served by delaying the effective date of this action.

List of Subjects in 7 CFR Part 981

Almonds, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 981 is amended as follows:

PART 981—ALMONDS GROWN IN CALIFORNIA

1. The authority citation for 7 CFR part 981 continues to read as follows:

Authority: Secs. 1–19, 46 Stat. 31, as amended; 7 U.S.C. 601–674.

2. Section 981.455 is amended by revising paragraph (b) to read as follows:

§ 981.455 Interhandler transfers.

* * * * *

(b) *Transfers of reserve credits.* A handler may transfer reserve credits to another handler after having filed with the Board, in accordance with § 981.474, a completed ABC Form 13/14 covering the almonds to be diverted to a noncompetitive outlet and all the documentation applicable thereto. Such a transfer does not relieve the transferring handler of any reserve obligations for the applicable crop year. The transferred credit shall not exceed the quantity needed by the receiving handler to cover that handler's reserve obligation. The Board shall complete the transfer upon receipt of an ABC Form 11 executed by both handlers. No transfer of reserve credits shall be made to satisfy a handler's inedible disposition obligation incurred pursuant to § 981.42(a).

* * * * *

Dated: April 25, 1991.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 91–10156 Filed 4–29–91; 8:45 am]

BILLING CODE 3410–02–M

Animal and Plant Health Inspection Service

9 CFR Parts 94 and 95

[Docket 90–252]

Importation of Animal Products and Byproducts From Countries Where BSE Exists

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: We are amending our regulations by adding a list of countries where bovine spongiform encephalopathy (BSE) exists, and by prohibiting or restricting the importation of certain fresh, chilled, and frozen meat, and certain other animal products and animal byproducts from ruminants which have been in a country in which BSE exists. This action is necessary to reduce the risk that BSE could be introduced into the United States. This change will affect persons seeking to import the articles described above.

DATES: Interim rule effective April 30, 1991. Consideration will be given only to comments received on or before July 1, 1991.

ADDRESSES: To help ensure that your written comments are considered, send an original and three copies to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket Number 90–252. Comments may be inspected at room 1141 of the South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. John Gray, Senior Staff Veterinarian, Import-Export Products Staff, VS, APHIS, USDA, room 756, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–7885.

SUPPLEMENTARY INFORMATION:

Background

A neurological disease of bovine animals and deer called bovine spongiform encephalopathy (BSE) has been identified in France, Great Britain, Northern Ireland, the Republic of Ireland, Oman, and Switzerland. Since the disease was first identified in 1986 there have been over 23,300 cattle on over 10,400 farms in Great Britain that have died or been destroyed as a result of BSE infection. BSE has also been found to affect a small number of deer in Great Britain. At the present time, BSE is not known to exist in the United States.

At our present state of knowledge about the disease, it appears that BSE in bovine animals and deer may be caused by the same agent that causes the disease scrapie in sheep and goats. The major means of spread of BSE appears to be through the use of ruminant feed containing meat and other products from ruminants infected with BSE, and through use of veterinary biologic products which contain byproducts from ruminants infected with BSE.

This rule prohibits or restricts the importation of certain meat, products, and byproducts from ruminants which have been in countries in which BSE exists. Some ruminant feed used in the United States contains imported

ruminant meat, products, and byproducts. Further, some imported ruminant byproducts are used in veterinary biologic products in the United States. BSE could become established in the United States if materials carrying the BSE agent, such as certain meat, animal products, and animal byproducts from ruminants in countries in which BSE exists, are imported into the United States and are fed to or injected into ruminants in the United States. Therefore, the importation of these ruminant meat, products, and byproducts poses a risk of the introduction of BSE into the United States.

The Animal and Plant Health Inspection Service (APHIS) has determined that to prevent the introduction of BSE into the United States, the importation of fresh, frozen, and chilled meat, and edible products other than meat, from ruminants that have been in a country in which BSE exists must be prohibited unless the following conditions have been met: (1) All bones and visually identifiable lymphatic tissue and nerve tissue have been removed from the meat or edible product other than meat; (2) the meat or edible product other than meat is from ruminants that have not been in any country in which BSE exists during a period of time when the country permitted the use of ruminant protein in ruminant feed; and (3) the ruminants from which the meat or other edible products to be imported are derived were examined prior to slaughter by a salaried veterinarian employed by the national government of the country in which the ruminants were slaughtered, and found not to display any signs indicative of a neurological disorder.

These conditions are imposed on the importation of fresh, frozen, and chilled meat, and edible products other than meat, from ruminants that have been in a country in which BSE exists for the following reasons. First, the BSE agent concentrates in nerve and lymphatic tissue and bone marrow. Lymphatic and nerve tissue that is not visually identifiable does not constitute a significant risk of introducing BSE into the United States. Second, ruminants that have never been fed ruminant protein are extremely unlikely to develop BSE. Finally, ruminants that display signs of neurological disorder pose a high risk of being infected with BSE.

To ensure that a proper examination is made by persons able to detect signs indicative of a neurological disorder, ruminants from which the meat or other edible products to be imported are derived must be examined prior to slaughter by a salaried veterinarian employed by the national government of the country in which the ruminants are slaughtered for any signs indicative of a neurological disorder.

Further, APHIS has determined that to prevent the introduction of BSE into the United States, the importation of bone meal, blood meal, meat meal or tankage, fat, glands, and offal from ruminants that have been in a country in which BSE exists must be prohibited. These products are commonly added to ruminant feed, and we wish to remove the possibility that these animal byproducts from ruminants that have been in a country in which BSE exists could be imported and added to ruminant feed in the United States.

Further still, APHIS has determined that to prevent the introduction of BSE into the United States, the importation of ruminant serum from ruminants that have been in a country in which BSE exists must be prohibited, except when imported under a permit for scientific, educational, or research purposes. Imported serum is occasionally used in veterinary biologic products in the United States, and ruminant serum from ruminants that have been in countries in which BSE exists potentially could infect animals susceptible to infection with BSE that are injected with products made from it.

The regulations in 9 CFR parts 94 and 95 (the regulations) govern the importation of animals, animal products, animal byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases. The regulations currently prohibit or restrict the importation of ruminants and swine; fresh, chilled, and frozen meat of ruminants and swine; and other specified animal products and animal byproducts that originate in or are shipped from a country where certain animal diseases exist.[1] We are adding restrictions for certain meat, products, and byproducts of the types described above from ruminants that have been in countries in which BSE exists, and we are listing France, Great Britain, Northern Ireland, the Republic of Ireland, Oman, and Switzerland as countries in which BSE exists. We are also adding definitions of "Administrator," "Animal and Plant Health Inspection Service," and "United States" in part 95.

[1] Animal diseases addressed by Part 94 include, but are not limited to, rinderpest, foot-and-mouth disease, fowl pest, Newcastle disease, African swine fever, and hog cholera.

Emergency Action

James W. Glosser, Administrator of the Animal and Plant Health Inspection Service, has determined that there is good cause for publishing this rule without prior opportunity for public comment.

BSE is a serious animal disease that has caused great loss to the cattle industry of Great Britain, and the introduction of this disease into the United States would cause great harm to the United States cattle industry. The restrictions contained in this interim rule must be implemented immediately to reduce the risk that BSE could be introduced into the United States through importation of certain meat, products, and byproducts from ruminants that have been in countries in which BSE exists.

Since prior notice and other public procedures with respect to this interim rule are impracticable and contrary to the public interest under these conditions, there is good cause under 5 U.S.C. 553 for making it effective upon publication in the **Federal Register.** We will consider comments that are received within 60 days of publication of this interim rule in the **Federal Register.** After the comment period closes, we will publish another document in the **Federal Register,** including discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

As an alternative to the provisions of this rule, we have considered taking no action, and enforcing the current import regulations. This alternative was

rejected because it would allow meat, animal products, and animal byproducts that might spread BSE to be imported into the United States

The provisions of this rule will not have a significant economic impact on large or small entities. The only businesses affected will be a small number of importers of meat, products, and byproducts of ruminants which have been in a country in which BSE exists. Alternative sources for these products are available in the United States.

In recent years no fresh, chilled, or frozen beef has been imported from France, Great Britain, Northern Ireland, Oman, or Switzerland. A small amount of beef was imported from the Republic of Ireland in recent years; the value of these imports for the period 1987–88 was only $1,300,000. Recently one plant in Northern Ireland has applied to export beef to the United States. If this plant is approved, it will bear additional deboning and preparation costs for meat exported to the United States, to ensure that the meat meets the requirements of this rule.

An exporter in Great Britain has recently expressed interest in exporting small amounts of meat from deer to the United States. The exporter would also have to bear additional deboning and preparation costs to ensure that the meat meets the requirements of this rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This interim rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 94

African swine fever, Animal diseases, Exotic Newcastle disease, Foot-and-mouth disease, Fowl pest, Garbage, Hog cholera, Imports, Livestock and livestock products, Meat and meat products, Milk, Poultry and poultry products, rinderpest, and Swine vesicular disease.

List of Subjects in 9 CFR Part 95

Animal byproducts, Animal diseases, Imports, Livestock and livestock products.

Accordingly, the regulations in 9 CFR parts 94 and 95 are amended as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), NEWCASTLE DISEASE (AVIAN PNEUMOENCEPHALITIS), AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 147a, 150ee, 161, 162, 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, and 134f; 31 U.S.C. 9701; 42 U.S.C. 4331, 4332; 7 CFR 2.17, 2.51, and 371.2(d).

2. A new § 94.18 is added to read as follows:

§ 94.18 Ruminant meat and edible products from ruminants that have been in countries where bovine spongiform encephalopathy exists.

(a) Bovine spongiform encephalopathy exists in the following countries:France, Great Britain, Northern Ireland, the Republic of Ireland, Oman, and Switzerland.

(b) The importation of fresh, frozen, and chilled meat, and edible products other than meat, from ruminants that have been in any country listed in paragraph (a) of this section is prohibited unless the following conditions have been met:

(1) All bones and visually identifiable lymphatic tissue and nerve tissue have been removed from the meat or edible product other than meat;

(2) The meat or edible product other than meat is from ruminants that have not been in any country listed in paragraph (a) of this section during a period of time when the country permitted the use of ruminant protein in ruminant feed; and

(3) The ruminants were examined prior to slaughter by a salaried veterinarian employed by the national government of the country in which the ruminants were slaughtered, and found not to display any signs indicative of a neurological disorder.

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

3. The authority citation for part 95 is revised to read as follows:

Authority: 21 U.S.C. 111; 31 U.S.C. 9701; 7 CFR 2.17, 2.51, and 371.2(d).

§ 95.1 [Amended]

4. The paragraph designations in § 95.1 are removed, the definitions are placed in alphabetical order, and new definitions of "Administrator," "Animal and Plant Health Inspection Service," and "United States" are added in alphabetical order to read as follows:

Administrator means the Administrator, Animal and Plant Health Inspection Service, or any individual authorized to act for the Administrator.

Animal and Plant Health Inspection Service means the Animal and Plant Health Inspection Service of the United States Department of Agriculture.

United States means the several States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other territories and possessions of the United States.

5. A new § 95.4 is added to read as follows:

§ 95.4 Bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants that have been in countries in which bovine spongiform encephalopathy exists.

The importation of bone meal, blood meal, meat meal or tankage, offal, fat, and glands from ruminants that have been in any country listed in § 94.18 of this chapter, is prohibited. The importation of serum from ruminants that have been in any country listed in § 94.18 of this chapter is prohibited, except that serum from ruminants may be imported for scientific, educational, or research purposes if the Administrator determines that the importation can be made under conditions that will prevent the introduction of bovine spongiform encephalopathy into the United States. Serum from ruminants imported in accordance with this section must be accompanied by a permit issued by the Animal and Plant Health Inspection Service in accordance with § 104.4 of this chapter, and must be moved and handled as specified on the permit.

Done in Washington, DC, this 24th day of April 1991.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1245

Patents and Other Intellectual Property Rights

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.